COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL/SMILOW CANCER HOSPITAL CARE CENTERS/SAINT FRANCIS HOSPITAL

Study Title: S1207, Phase III Randomized, Placebo-Controlled Clinical Trial Evaluating the Use of Adjuvant Endocrine Therapy +/- One Year of Everolimus in Patients with High-Risk, Hormone Receptor-Positive and HER2/neu Negative Breast Cancer.
e3 Breast Cancer Study- **e**valuating **e**verolimus with **e**ndocrine therapy
Principal Investigator: Andrea Silber, MD
Principal Investigator's Phone Number: (203) 785-2876
24-Hour Phone Number: (203) 785-4191
Principal Investigator's Mailing Address: 300 George St, Suite 120, New Haven, CT 06511

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you are a woman/man with hormone responsive breast cancer that has already been removed by surgery and you have completed any required chemotherapy or radiation.

Why is this study being done?

The purpose of this study is to see whether treatment with everolimus plus hormone treatment after chemotherapy will increase the time without your cancer returning. The current standard treatment after chemotherapy is hormone treatment alone. Everolimus is a drug currently approved for the treatment of patients with advanced or metastatic kidney or breast cancer. It is considered investigational for non-metastatic breast cancer patients. In this study you will get hormone treatment with either everolimus or with placebo (a pill with no medication). The combination of hormone-treatment and everolimus is experimental in patients with breast cancer.

How many people will take part in the study?

About 1,900 people will take part in this study.

What will happen if I take part in this research study?

Before you begin the study …
You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Medical history risk and physical examination,
- Blood tests for blood counts and to test your kidney and liver function,
- Blood tests to check your blood sugar (glucose) and lipids (cholesterol and triglycerides),
- Required submission of blood and tissue specimens to a central laboratory for research purposes. The tissue will be taken from the tissue that was already removed as part of your surgery. The blood will be about 3-4 teaspoons and will be taken at the same time as your lab tests. You will not need an additional needle stick. These will be used for lab tests to look at how different aspects of your genetics and of your breast cancer may relate to choosing the best treatments for patients in the future. Additionally, at the end of this form you can also choose whether your specimens may be kept for use in similar kinds of lab studies in the future.

Positive results of Hepatitis will be reported to CT Department of Public Health.

During the study …
If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

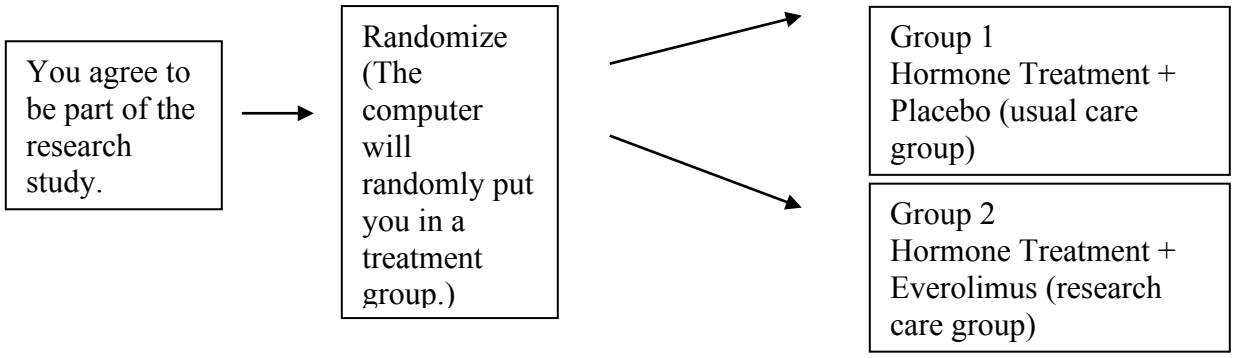
- Physical exam every six weeks for Reporting Periods 1, 2 and 6 and every twelve weeks for Reporting Periods 3-5,
- Blood tests for blood counts and to test your kidney function every six weeks for Reporting Periods 1, 2 and 6 and every twelve weeks for Reporting Periods 3-5,
- Blood tests to check your blood sugar (glucose) and lipids (cholesterol and triglycerides) every six weeks for Reporting Periods 1, 2 and 6 and every twelve weeks for Reporting Periods 3-5. Your study doctor may need to place you on additional medication to control your blood sugar and lipid levels.
- You may have a cancer relapse despite all efforts. If your cancer relapses and you and your physician decide you should have a biopsy as part of your usual cancer care, part of the tissue extracted from this biopsy must be submitted to researchers to learn more about cancer relapse.

This research study has two study treatment groups.

- One group will get the usual hormone treatment to treat their cancer plus a placebo (a pill with no medicine).
- The other group will get the usual hormone treatment plus a research drug called everolimus.

A computer will randomly put you in one of these study groups. You have a 50/50 chance of being placed into either group. This is done because no one knows if one treatment is better than the other. Once you are put in one group, you cannot switch to the other group. Neither you nor your doctor can choose or know which group you will be in.

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



You will take two pills once a day by mouth with a glass of water. The study drug should be taken in the morning after no more than a light fat-free meal. Tablets must be swallowed whole and not chewed or crushed. Due to interaction with everolimus, you must not consume grapefruit or grapefruit juice while on study. You must immediately inform your study doctor if you begin any new medications while on study drug.

You will record the number of pills you take each day and any side effects you experience on a calendar. For the first 6 weeks, your doctor's office will call you to see how you are doing on the weeks that you don't have visits scheduled. You should bring your calendar with you each time you have a doctor's visit. During your visits, your pills will be counted and your calendar reviewed. For this study, each six-week treatment period is called a reporting period for Reporting Periods 1, 2 and 6. Reporting Periods 3-5 are twelve week treatment periods. Treatment will continue for six reporting periods (54 weeks) as long as you are able to tolerate treatment and your cancer hasn't returned. All treatment can be given without being admitted to a hospital.

You will also get one of the standard types of endocrine treatment given over a period of 5-10 years. You and your doctor must agree to one of the options for endocrine treatment outlined in the study. The doctor will monitor you using standard methods.

How long will I be in the study?

You will be asked to take the study drug for six-reporting periods (54 weeks), or until your side effects become too great, or until your cancer returns. While you are receiving study treatment, you will need to come to the clinic for doctor visits every six weeks for the first 2 reporting

periods and the last reporting period (6), and every twelve weeks for the reporting periods 3-5 while on treatment. After you are finished with the study treatment, you will return to the clinic every six months for the first two years and then yearly thereafter until 10 years after beginning the trial.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the study drug can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. 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 also is a risk of death.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to everolimus/placebo drug include those which are:

COMMON, SOME MAY BE SERIOUS In 100 people receiving everolimus, more than 20 and up to 100 may have:
• **Anemia which may require blood transfusion** • **Diarrhea** • **Sores in the mouth which may cause difficulty swallowing** • **Tiredness** • **Bruising, bleeding** • **Rash**

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving everolimus, from 4 to 20 may have:

- **Pain**
- **Dry mouth, skin**
- **Nausea, vomiting**
- **Swelling of the arms, legs**
- **Fever**
- **Infection, especially when white blood cell count is low**
- **Weight loss, loss of appetite**
- **Dizziness, headache**
- **Changes in taste**
- **Difficulty sleeping**
- **Cough, shortness of breath**
- **Nose bleed**
- **Swelling of the lungs which may cause shortness of breath**
- **Itching, acne**
- **Change in or loss of some or all of the fingernails or toenails**

RARE, AND SERIOUS

In 100 people receiving everolimus, 3 or fewer may have:

- **Non-healing surgical site**
- **Kidney damage which may require dialysis**

Risks and Side effects related to hormone treatment (anastrozole, exemestane, goserelin acetate, letrozole, leuprolide acetate or tamoxifen) include those which are:

COMMON, SOME MAY BE SERIOUS

In 100 people receiving hormone treatment, more than 20 and up to 100 may have:

- **Pain and/or headache**
- **Tiredness**
- **Increased sweating**
- **Hot flashes, flushing**
- **Swelling of arms, legs**
- **Change in sexual desire and/or abnormal sexual function**
- **Depression, mood swings**
- **Shrinkage of the breast**
- **Vaginal discharge and/or abnormal menstrual period**
- **Acne, dandruff**
- **Nausea, vomiting**
- **Redness or swelling at the site of injection**
- **Difficulty sleeping**
- **Painful urination**

OCCASIONAL, SOME MAY BE SERIOUS

In 100 people receiving hormone treatment, from 4 to 20 may have:

- **Constipation, diarrhea, loss of appetite, heartburn**
- **Loss of bone tissue, broken bone, or decreased height**
- **Dizziness**
- **High blood pressure which may cause blurred vision**
- **Swelling of the liver which may cause belly pain**
- **Worry/anxiety/thoughts of suicide**
- **Hair thinning**
- **Fluid around lungs**
- **Heart attack or heart failure which may cause shortness of breath, swelling of ankles, and tiredness**
- **Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat**
- **Diabetes**
- **Stroke which may cause paralysis, weakness**
- **Kidney damage which may cause swelling, may require dialysis**
- **Shortness of breath**
- **Anemia, which may require blood transfusions**
- **Weight gain**

OCCASIONAL, SOME MAY BE SERIOUS (contd.)

In 100 people receiving hormone treatment, from 4 to 20 may have:

- **Shrinkage of testis**
- **Cough**
- **Rash**
- **Blood clot which may cause swelling, pain, shortness of breath**
- **Damage to the liver which may cause bleeding**
- **Breast tenderness, pain**
- **Cloudiness of the eye, visual disturbances**

RARE, AND SERIOUS

In 100 people receiving hormone treatment, 3 or fewer may have:

- **Severe skin rash with blisters and can involve inside of mouth and other parts of the body, fever**
- **Vaginal bleeding**
- **A new cancer resulting from treatment of earlier cancer**
- **Seizure**
- **Stroke**
- **Cancer of the uterus (or womb)**

Reproductive risks: You should not become pregnant or father a baby while on this study and for at least 12 weeks following completion of treatment because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study and for at least 12 weeks following completion of treatment. It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study. Women who become pregnant or think they might be pregnant must inform their treating physician immediately. Pregnancy requires a woman to come off protocol treatment immediately.

The study drug could potentially have an effect on the female menstrual cycle (period). Females being treated with everolimus may experience an interruption of their period. This interruption may last for several months and can resolve with no change in treatment.

There is a slight chance that the levels of certain hormones could be affected by the study drug.

The study drug may interact with other medications (i.e. certain CYP3A4 inducers or inhibitors and ACE inhibitors). You should tell your study doctor about all medications (over the counter, herbal, and prescription) you are currently taking and check with your study doctor before beginning any new medications.

Vaccines help protect people from certain illnesses. There is a chance that receiving blinded drug could interfere with any vaccinations you receive. Some vaccines are made from live bacteria or live viruses. You cannot receive this kind of vaccine (for example FluMist™ or BCG) for seven days prior to going on study or during the study.

Report any new cough or breathing problems right away.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While doctors hope the study drug will be more useful against cancer compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about blinded drug as a treatment for cancer. This information could help future cancer patients.

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

Your other choices may include:
- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment

Talk to your doctor about your choices before you decide if you will take part in this study.

Confidentiality

Information about your study participation will be entered into your Electronic Medical Record (EMR). Once placed in your EMR, these results are accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g. health insurance company, disability provider.)

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

The protected health information that will be collected in this study includes demographics, medical history, physical examinations, routine lab tests, review of adverse events and

medications you take (past and present), CT scans, pregnancy tests, blood samples for research purposes, blood samples to test your kidney and liver function, blood samples to check your blood sugar and lipids, tissue samples for research purposes, information recorded in study questionnaires, survival follow-up information and records about any study drug(s) that you received.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Local Institutional Review Board (IRB)
- SWOG
- NRG Oncology (This study was originally conducted with the National Surgical Breast and Bowel Project (NSABP). NSABP has joined with two other clinical trials groups to form NRG Oncology as required by the National Cancer Institute.)
- Novartis Pharmaceuticals (supplier of everolimus) or any subsequent pharmaceutical collaborator and their authorized agents
- ECOG-ACRIN
- Alliance
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- The Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials.
- A Data Safety and Monitoring Committee (DSMC), an independent group of experts will be reviewing the data from this research throughout the study.
- Local governmental agencies in other countries when the study drug may be considered for approval (Non-U.S. Institutions).
- The U.S. Department of Health and Human Services (DHHS) agencies
- Your providers who are participants in the Electronic Medical Record (EMR) system
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The study doctor, Dr. Andrea Silber, and the Yale study team
- The U.S. Food and Drug Administration (FDA). This is done so that the FDA can review information about the new drug product involved in this research. The information may also be used to meet the reporting requirements of drug regulatory agencies.
- Drug regulatory agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Health care providers who provide services to you in connection with this study.
- Laboratories and other individuals and organizations that analyze your health information in connection with this study, according to the study plan.
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure

that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale-New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

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.

Withdrawing Your Authorization to Use and Disclose Your Health Information
You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to Dr. Andrea Silber at the Yale University, 300 George Street, Suite 120, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

The parts of the research consisting of keeping research records will be paid by those organizing and conducting the research. The research requires that you receive certain standard medical tests and examinations. These standard tests and examinations will be charged in the usual way.

A pharmaceutical collaborator will supply the investigational agent everolimus or placebo at no charge while you take part in this study. The pharmaceutical collaborator does not cover the cost of getting the everolimus or placebo ready and giving it to you, so you or your insurance company may have to pay for this.

Even though it probably won't happen, it is possible that the pharmaceutical collaborator may not continue to provide everolimus or placebo for some reason. If this were to happen the study would close.

The endocrine therapy received during this trial is not experimental. It is considered a standard treatment for this type of cancer. The costs of these treatments are not paid for by the study, and you and/or your health plan/insurance company will need to pay for the cost of these endocrine therapy treatments.

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

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://www.cancer.gov/about-cancer/treatment/clinicaltrials/paying/insurance. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

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

It is important that you tell your study doctor, Dr. Andrea Silber, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at (203) 785-2876.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment. Novartis will not pay any money to you or your medical bills.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

We will tell you about important new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor, Dr. Andrea Silber, at (203) 785-2876.

For questions about your rights while taking part in this study, call the Yale University Institutional Review Board (a group of people who review the research to protect your rights) at (203) 785-4688.

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

*You may also call the Operations Office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the continental US only).

Please note: This section of the informed consent form is about additional research studies that are being done with people who are taking part in the main study. You may take part in these additional studies if you want to. You can still be a part of the main study even if you say 'no' to taking part in any of these additional studies.

You can say "yes" or "no" to each of the following studies. Please mark your choice for each study.

FUTURE CONTACT
I agree to allow my study doctor, or someone approved by my study doctor, to contact me regarding future research involving my participation in this study.

Yes **No**

Additionally, we would also like to keep left over tissue and blood specimens for future, unspecified scientific testing. An additional consent form and information is attached for this purpose.

Consent Form for Use of Specimens for Research

About Using Specimens for Research

We would like to use these specimens for future research. If you agree, these specimens will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How are Specimens Used for Research" to learn more about specimen research.

Your specimens may be helpful for research whether you do or do not have cancer. The research that may be done with your specimens is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your specimens will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

The choice to let us keep the left over specimens for future research is up to you. No matter what you decide to do, it will not affect your care.

If you decide now that your specimens can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your specimens. Then any specimens that remain will no longer be used for research.

In the future, people who do research may need to know more about your health. While SWOG may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes specimens are used for genetic research (about diseases that are passed on in families). Even if your specimens are used for this kind of research, the results will not be put in your health records.

If your confidential genetic information is discovered, you may suffer from genetic discrimination. Genetic discrimination occurs if people are treated unfairly because of differences in their genes that increase their chances of getting a certain disease. In the past, this could have resulted in the loss of health insurance or employment. Because of this, The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, was passed by Congress to protect Americans from such discrimination. The new law prevents discrimination from health insurers and employers. This act was signed into federal law on May 21, 2008, and went into effect May 2009. This law does not cover life insurance, disability insurance and long-term care insurance.

Your specimens will be used only for research and will not be sold. The research done with your specimens may help to develop new products in the future.

Benefits

The benefits of research using specimens include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

Risks

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

Making Your Choice

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No." If you have any questions, please talk to your doctor or nurse, or call our research review board at IRB's phone number.

No matter what you decide to do, it will not affect your care.

1. **My specimens may be kept for use in research to learn about, prevent, treat or cure cancer.**
   Yes **No**

2. **My specimens may be kept for use in research about other health problems (for example: diabetes, Alzheimer's disease, or heart disease).**
   Yes **No**

3. **Someone may contact me in the future to ask me to allow other uses of my specimens.**
   Yes **No**

If you decide to withdraw your specimens from a SWOG Specimen Repository in the future, a written withdrawal of consent should be submitted through your study doctor to the SWOG Operations Office. Please designate in the written withdrawal whether you would prefer to have the specimens destroyed or returned to the study doctor.

Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

You will get a copy of this form. If you want more information about this study, ask your study doctor.

Signature

I have been given a copy of all 18 pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Participant (or their legally authorized representative)_____

Date _____

Person obtaining consent (print name)	Signature	Date
Interpreter/ Witness (print name) – only if applicable, otherwise blank	Signature	Date

Specimen Consent Supplemental Sheets

How are Specimens Used for Research?

Where do specimens come from?

A specimen may be from a blood sample or from bone marrow, skin, toenails or other body materials. People who are trained to handle specimens and protect donors' rights make sure that the highest standards of quality control are followed by SWOG. Your doctor does not work for SWOG, but has agreed to help collect specimens from many patients. Many doctors across the country are helping in the same way.

Why do people do research with specimens?

Research with specimens can help to find out more about what causes cancer, how to prevent it, how to treat it, and how to cure it. Research using specimens can also answer other health questions. Some of these include finding the causes of diabetes and heart disease, or finding genetic links to Alzheimer's.

What type of research will be done with my specimen?

Many different kinds of studies use specimens. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs. Some research looks at diseases that are passed on in families (called genetic research). Research done with your specimen may look for genetic causes and signs of disease.

How do researchers get the specimen?

Researchers from universities, hospitals, and other health organizations conduct research using specimens. They contact SWOG and request samples for their studies. SWOG reviews the way that these studies will be done, and decides if any of the samples can be used. SWOG gets the specimen and information about you from your hospital, and sends the specimen samples and some information about you to the researcher. SWOG will not send your name, address, phone number, social security number or any other identifying information to the researcher.

Will I find out the results of the research using my specimen?

You will not receive the results of research done with your specimen. This is because research can take a long time and must use specimen samples from many people before results are known. Results from research using your specimen may not be ready for many years and will not affect your care right now, but they may be helpful to people like you in the future.

Why do you need information from my health records?

In order to do research with your specimen, researchers may need to know some things about you. (For example: Are you male or female? What is your race or ethnic group? How old are you? Have you ever smoked?) This helps researchers answer questions about diseases. The information that will be given to the researcher may include your age, sex, race, diagnosis, treatments and family history. This information

is collected by your hospital from your health record and sent to SWOG. If more information is needed, SWOG will send it to the researcher.

Will my name be attached to the records that are given to the researcher?

No. Your name, address, phone number and anything else that could identify you will be removed before they go the researcher. The researcher will not know who you are.

How could the records be used in ways that might be harmful to me?

Sometimes, health records have been used against patients and their families. For example, insurance companies may deny a patient insurance or employers may not hire someone with a certain illness (such as AIDS or cancer). The results of genetic research may not apply only to you, but to your family members too. For disease caused by gene changes, the information in one person's health record could be used against family members.

How am I protected?

SWOG is in charge of making sure that information about you is kept private. SWOG will take careful steps to prevent misuse of records. Your name, address, phone number and any other identifying information will be taken off anything associated with your specimen before it is given to the researcher. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the research process will not have access to results about any one person which will help to protect your privacy.

What if I have more questions?

If you have any questions, please talk to your doctor or nurse, or call our research review board at (203) 785-4688.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator Dr. Andrea Silber at (203) 785-2876.

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.