

<b>Principal Investigator:</b>	Howard Hochster, MD	<b>HIC #:</b>	1507016151
<b>Funding Source:</b>	ECOG-ACRIN, NCI	<b>Sponsor Protocol Number:</b>	EAY131
<b>Sponsor ICF Template Version:</b>	Addendum 4	<b>Protocol Version:</b>	Addendum 4
<b>Sponsor ICF Template Date:</b>	01-July-2016	<b>Protocol Date:</b>	01-July-2016

**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 for Study Participants: Screening for treatment assignment  
based on genetic testing**

**Principal Investigator:** Howard Hochster, MD

**Principal Investigator's Phone Number:** (203) 785-2360

**24-Hour Phone Number:** (203) 785-4191

**Principal Investigator's Mailing Address:** 333 Cedar Street, PO. Box 208028, New Haven, CT  
06520-8028

**Official Study Title for Internet Search on**

**<http://www.ClinicalTrials.gov>: EAY131: Molecular Analysis for Therapy  
Choice (MATCH)**

Version Date: July 1, 2016

**What is the usual approach to my cancer?**

You are being asked to take part in this study because you have cancer that has become worse following treatment, or no standard therapy exists for your type of cancer. People who are not participating in a study would usually be treated with chemotherapy, radiation, or surgery. Sometimes, combinations of these could be used. For people who receive the usual approach for this cancer, symptoms may be reduced and the tumor could stop growing for several months or more.

**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 described above
- you may choose to take part in a different study, if one is available
- you may choose to have your tumor tested at a commercial or other laboratory
- or you may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms.

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## Why is this study being done?

The purpose of this study is to test any good and bad effects of several different study drugs or drug combinations, each of which targets specific genetic changes found in some cancers. The first step is to determine if you can participate in this study (screening step). The purpose of this screening step is to perform tests on your tumor cells to find out if your cancer has a gene change or mutation targeted by one or more of the drugs used in this study. The tests done on your tumor are investigational, and are done for the purpose of assigning a treatment to a MATCH substudy. Approximately 3000 people will be biopsied and have their tumor tissue evaluated for this screening study. Participants in the screening study that have a biopsy result that matches a substudy will be invited to participate in a specific substudy. It is expected that approximately 35 participants will take part in each of the MATCH substudies. We anticipate that 15-20% of patients will have a mutation that can be matched with a treatment in this study.

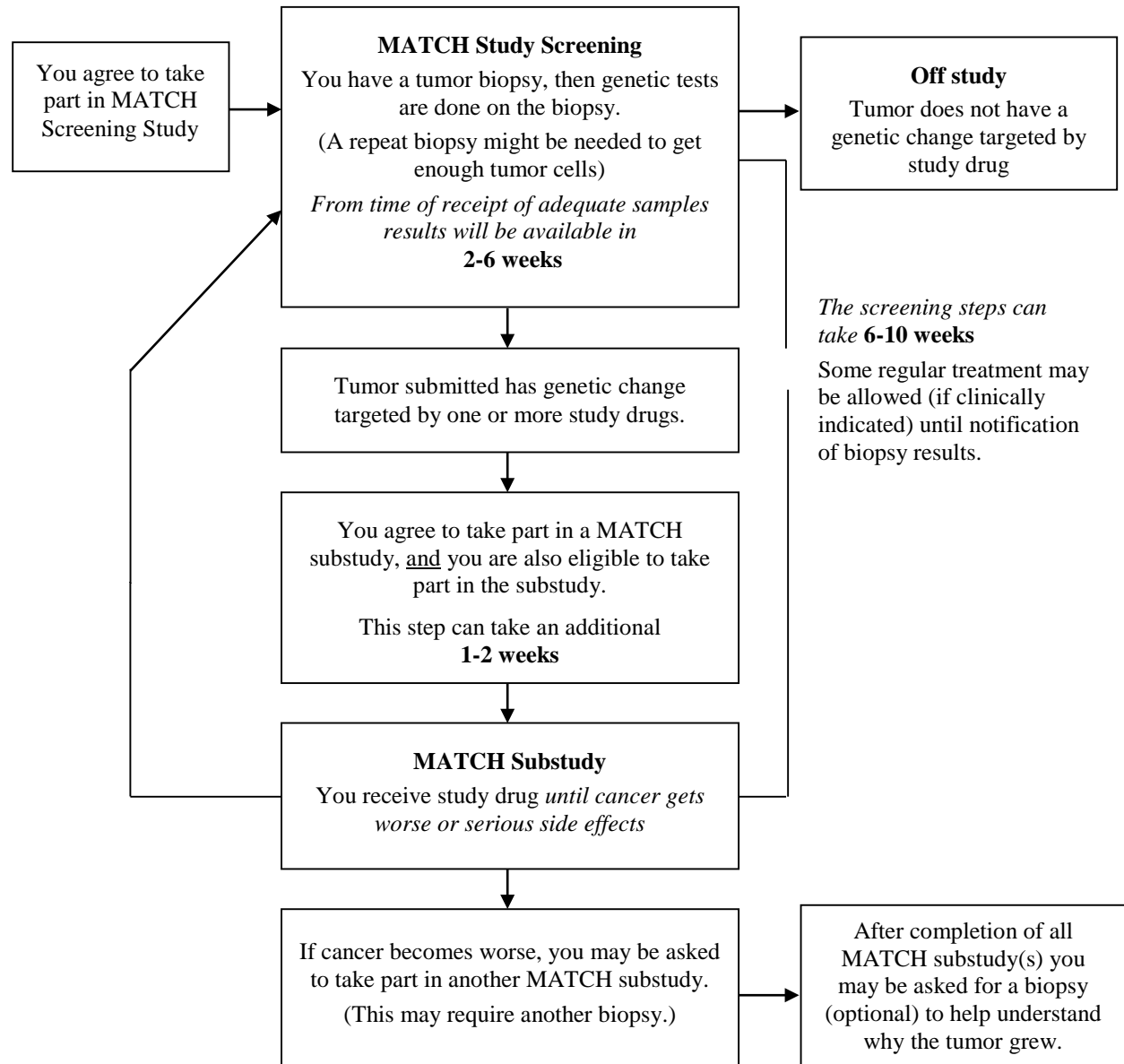
## What are the study groups?

All participants in this screening study are required to have a sample of their tumor tested for genetic changes that are targeted by drugs used in the substudies. The tissue may be from a biopsy performed after registration to the screening step, or, if available, from a procedure done for clinical care if you have not had additional treatment.

If your tumor has a genetic change or mutation that is targeted by one or more of the drugs used in this study, you will be asked to participate in that part of the study (also referred to as a substudy). The substudy information will be provided in a separate consent form. Your doctor will discuss the study with you.

If your tumor does not have a genetic change for which we have study drug(s) or if the available study drug(s) would put you at risk due to other health conditions, you will no longer be in the study.

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## How long will I be in this study?

The screening portion of this research study requires that the tissue obtained from a biopsy of your cancer is tested to see if it has certain genetic changes. The results of the testing will tell us if there is an appropriate substudy for you. In other words, you can only join a substudy testing of an investigational drug if your cancer has one of the genetic changes that is being studied.

Please know that this testing takes time. While the testing is being done it is possible that you could be off treatment for your cancer for at least 6-10 weeks. This is because it can take up to 2 weeks to have the biopsy done. Then, it can take 2-6 weeks for the genetic testing to be performed on the biopsy tissue. And finally, if we learn that your cancer has a genetic change that tells us there is an appropriate substudy, it can take additional 1-2 weeks to make sure you still meet the requirements to participate in that substudy. You should discuss with your doctor if it is ok for you to be off treatment for your cancer while this testing is being done.

If there is a problem with scheduling the biopsy, or with the tumor sample, or with the test procedure, getting the results of the testing could take longer.

We will work very hard to get the testing done as quickly as possible. The time periods mentioned above are estimates. It is possible that you could be assigned to and receive treatment sooner than 6-8 weeks. But, it is also possible that it could take longer.

If you participate in one of the substudies you will take the study drug that is being evaluated until your cancer becomes worse, or you have side effects and can no longer tolerate the study drug. At that point it is possible that you will be asked to take part in one or more other substudies that are part of MATCH. This may require another biopsy to obtain additional tumor tissue to test for any new genetic changes that occur in the cancer that are targeted by other drugs used in the study.

After you stop using a MATCH study drug for the reasons described above, you may be asked to have a biopsy to collect tissue for research studies. This biopsy is optional. If you agree to have the biopsy, more information about it will be provided in a separate consent form.

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

You will need to have the following extra exams, tests and procedures to find out if you can be in the study:

- You may have a biopsy of your tumor (bone marrow examination if you have myeloma or lymphoma), which will be tested for genetic changes. If this biopsy does not contain enough tumor tissue for the genetic tests to be performed, a repeat biopsy will be needed if you still wish to continue in the study. For your first screening, tumor tissue from a recent previous surgery or biopsy may be able to be used if it was collected recently and you have not received any targeted treatment or responded to a chemotherapy treatment since it was collected. Your study doctor will be given the results of the genetic tests of

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your tumor and will share them with you. The results may also be placed in your medical record. Some personal identifying information, including your name and date of birth, will be sent with the tissue to the laboratories doing the genetic tests. This is to ensure the results are reported correctly to your doctor.

- Additional exams or procedures may be required, similar to those that are done before any type of chemotherapy, if your tumor screening shows you may be able to participate in a MATCH study treatment. The study treatment information will be discussed in a separate Consent Form.
- If your cancer becomes worse during treatment with the study drug(s), you may be asked to take part in another MATCH study treatment. Your study doctor will discuss this with you. Another biopsy may be required and will be tested to determine if your tumor has new genetic changes and if a different MATCH study treatment is available for your cancer. This testing will be similar to previous testing done in the initial screening step. Your study doctor will be given the results of these new genetic tests and will share them with you. There may be additional exams or procedures required for another MATCH study treatment. These will be discussed in a separate Consent Form.

Before any biopsy procedure, you will sign a separate surgical consent form from the institution where the biopsy procedure is done.

Any leftover tissue from any of the tissue samples submitted during the study will be biobanked (saved in a facility) with your permission. This is discussed later in “Additional Studies” section of this consent form. Your privacy is very important and the researchers will make every effort to protect it. The banked samples will be identified by a unique code. Researchers will not be given your name or other personal identifiers.

You may have imaging exams done as part of your cancer care (i.e. PET scan, CT scan, MRI, Ultrasound). Those images will be sent to the ECOG-ACRIN Cancer Research Group for research. Researchers will study the scans to learn more about how to use the images to evaluate your disease.

## **What possible risks can I expect from taking part in screening for this study?**

If you choose to take part in this study, there are some medical risks:

- Because the study requires additional tests, including the biopsy, you may lose time at work or home and spend more time in the hospital or doctor’s office than usual
- Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, pain at the biopsy site, which can be treated with regular pain medications, and bruising. Rarely, an infection or need for hospitalization may occur.

There are also some risks associated with genetic testing:

- There are protections in place that restrict who can see the results of your genetic tests. However, there remains 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

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that someone will identify you is very small, but the risk may increase in the future as people come up with 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. There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

- It is possible that a mutation found in the tumor DNA is also a mutation in your normal tissue (inheritable, or passed down in families). Since we are not testing normal tissue, we cannot tell if an abnormal gene in the tumor could also be in your normal (non-tumor) cells. The test results sent to your doctor will have a cover sheet listing gene mutations that are possibly inherited. Your study doctor will discuss this with you. If your test results show that you have gene mutations that are possibly inherited, your doctor may recommend that you meet with a genetic counselor and, if warranted, undergo further genetic testing on non-tumor tissue to determine if the mutation is inherited. This type of testing is considered standard care and is not part of this study.
- As with all medical screening tests, there is a chance of a false positive or a false negative result. A “false positive” refers to the identification of a genetic change that is not present. A “false negative” is the failure to find a genetic change that indeed exists. The tests have been designed to ensure that the possibility of incorrect results is low. Either a false positive or a false negative test would mean that your treatment assignment may not include the correct targeted treatment.

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

It is not possible to know at this time if the study approach to screening your tumor tissue to assign treatment is better than the usual approach, so this study may or may not help you. This study will help researchers learn things that will help people in the future.

### **Can I stop taking part in this screening study?**

Yes. You can decide to stop being part of this research project at any time. If you decide to stop for any reason or withdraw from the study, it is important to let the study doctor know as soon as possible. However, once you have had a biopsy and tissue is submitted, it is not possible to stop the screening test and having results sent to your study doctor. If you decide to not participate in this study after the results are received, they may still be a part of your medical records, and may possibly affect your future care. You can ask your study doctor whether or not this information will be included in your medical records. 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.

Your doctor will talk with you about going off the study if:

- Your health changes and the study is no longer in your best interest

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- New information becomes available that may affect your health or your willingness to continue in the study.
- The study is stopped by the sponsor, Institutional Review Board (IRB) or the Food and Drug Administration (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 Yale University Institutional Review Board at (203) 785-4688.

## **What are the costs of taking part in the screening part of this study?**

You will not pay for the biopsy costs if they are to collect tissue for this screening only. You will not pay for the costs of the genetic test required to see if you are eligible to participate in the treatment part of the study, or for any other research studies done on the submitted tissue samples. You and/or your health plan/insurance company will need to cover all of the other costs, including the cost of tests, procedures, or medicines to manage any side effects of your biopsy, unless you are told that certain tests are being done 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.

If screening shows you are eligible to get study drug(s), any costs of being in the study will be discussed along with details of your treatment.

You will not be paid for taking part in any part of this study, including screening.

## **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. 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 seek payment for this even though you are in a study.

## **Who will see my medical information?**

To help protect your privacy, ECOG-ACRIN has obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, ECOG-ACRIN cannot be forced (for example, by court subpoena) to disclose information that may

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identify you in any federal, state or local civil, criminal, administrative, legislative or other proceeding. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, if your information is not required to be given out by law, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database. Once the data are in the centralized database, they may be used for future health research beyond cancer. Investigators will be granted access to this data only for projects approved by the data access committee and must also promise to keep your data secure.

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.)

The protected health information includes demographics, medical history, physical examinations, routine lab tests, review of adverse events and medications you take (past and present), vital signs, eye examinations, MRI scans, CT scans, ECHOs or MUGAs, pregnancy tests, blood samples for research purposes, information recorded in study questionnaires, survival follow-up information and records about any study drug(s) that you received.

There are other organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- ECOG-ACRIN Cancer Research Group (ECOG-ACRIN)
- Southwest Oncology Group (SWOG)
- NRG Oncology (NRG)
- Alliance for Clinical Trials in Oncology (Alliance)
- Children's Oncology Group (COG)
- The drug companies supporting the study.
- The Institutional Review Board (IRB), a group of people who review the research with the goal of protecting the people who take part in the study.
- The U.S. Food and Drug Administration (FDA) and the National Cancer Institute
- Imaging and Radiation Oncology Core (IROC)
- Other central laboratories testing your tissue samples, the central reviewers and the Biobank
- Other regulatory agencies and/or their designated representatives



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- Cancer Trials Support Unit (CTSU), a service sponsored by NCI to provide greater access to cancer trials
- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University and the Human Investigation Committee (the committee or Institutional Review Board that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential
- 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, Howard Hochster, MD, 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.

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### **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 Howard Hochster, MD at Yale University, 333 Cedar Street, 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.

### **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 the study doctor, **Howard Hochster, MD at (203) 785-2360**.

### **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 these optional studies 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.

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Circle your choice of “yes” or “no” for use of your blood and tissue as listed below.

### **Optional sample collections for biobanking for possible future studies**

Researchers are trying to learn more about cancer and other health problems. Much of this research is done using samples of tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure cancer and/or other health problems.

At this time, we are requesting that you consider allowing the samples of your tissue and blood to be kept for research projects that may be done at a later date. These specimens will be stored in a “biobank”.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you agree to allow your samples to be banked for research and there is enough left over sample, we may do additional study of the DNA and RNA in your tumor to see if other molecular features may have influence on response or lack of response to the treatment, as well as possible explanations why your tumor grew. To do this, whole blood and plasma will also be sequenced to compare to tumor sequencing. These studies will be done in research laboratories, and your identifying data will be removed so these results will not be returned to you.

### **WHAT IS INVOLVED?**

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

1. About 2-3 tablespoons of blood will be collected from a vein in your arm. This amount of blood will be collected each time tissue is submitted for screening. This blood is only for additional research purposes, such as to see if genomic changes in your tumor can also be found in the blood.
2. A sample from the tissue that was collected from a previous biopsy or surgery (or from bone marrow examination for patients with myeloma) will be sent to the Biobank to be used for possible research studies.
3. Samples remaining after the screen assays are performed may be stored in the Biobank.
4. The blood and tissue 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.
5. A committee of experts from the National Clinical Trials Network (NCTN) and the National Cancer Institute will review requests to use the samples for research. All research projects using these samples will also be reviewed by an ethics or institutional review board 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.

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6. 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.
7. Results and data generated from the research may be placed in centralized storage systems called databases. It is possible that some of your genetic information and your health information may be placed in these databases without your name or identifiers.

Once the data are in the centralized database, they may be used for future health research beyond cancer. Investigators will be granted access to this data only for projects approved by the data access committee and must also promise to keep your data secure.

## **WHAT ARE THE POSSIBLE RISKS?**

1. The most common risks related to drawing blood from your arm are brief pain and possibly a bruise. Rarely, an infection may occur.
2. 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.
3. 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 increase in the future as people come up with new ways of tracing information.
4. 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 from the Biobank 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 ECOG-ACRIN staff with access to the list must sign an agreement to keep your identity confidential.
3. Researchers to whom ECOG-ACRIN send 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.

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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 allowing your samples to be used for research.

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 FOR THE ADDITIONAL, OPTIONAL RESEARCH STUDIES?**

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, Howard Hochster, MD at (203) 785-2360 who will let the researchers know. 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, **Howard Hochster, MD at (203) 785-2360.**

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

## **SAMPLES FOR FUTURE LABORATORY STUDIES:**

May we collect blood and have tissue from previous surgeries or biopsies for future research studies?

- **I agree to provide additional samples for research.**

**YES**

**NO**

<b>Principal Investigator:</b>	Howard Hochster, MD	<b>HIC #:</b>	1507016151
<b>Funding Source:</b>	NCI	<b>Sponsor Protocol Number:</b>	EAY131
<b>Sponsor ICF Template Version:</b>	Addendum 3	<b>Protocol Version:</b>	Addendum 3
<b>Sponsor ICF Template Date:</b>	25-May-2016	<b>Protocol Date:</b>	25-May-2016

May we keep any tissue left over from the screening assays for future research studies?

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

**YES**

**NO**

### **My signature agreeing to take part in the master screening 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 screening study and any additional studies where I circled 'yes'.

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.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, **Howard Hochster, MD at (203) 785-2360**. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688.

Participant's signature \_\_\_\_\_

Date of signature \_\_\_\_\_

Signature of person(s) conducting the informed consent discussion

\_\_\_\_\_

Date of signature \_\_\_\_\_

\_\_\_\_\_  
Interpreter/Witness (print name)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

– only if applicable, otherwise blank