FOX CHASE CANCER CENTER
TEMPLE HEALTH

FOX CHASE CANCER CENTER
AT TEMPLE UNIVERSITY HOSPITAL
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INFORMED CONSENT DOCUMENT

GI-063: Phase I study of drug-eluting irinotecan beads (DEBIRI) in refractory metastatic colorectal cancer with liver-only or liver-predominant disease

Principal Investigator: Efrat Dotan, MD
Temple University Hospital Site Investigator : Juhi Mittal, MD

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 should discuss your decision with your friends and family. You will 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 research study because you have metastatic colorectal cancer that involves only or mainly the liver.

The sponsor of this study is Dr. Efrat Dotan at Fox Chase Cancer Center with support from BTG PLC.

Why is this research study being done?

The purpose of this research study is to evaluate the safety and tolerability of drug-eluting irinotecan beads (DEBIRI) in the treatment for colorectal cancer that has spread to the liver and did not respond to treatment with standard chemotherapy. DEBIRI will be given directly into the liver using tiny beads that have been loaded with irinotecan, a chemotherapy drug. This new and unique treatment is delivering the chemotherapy directly to the tumor area inside the liver instead of to the whole body as with systemic delivery of the drug.

We hope to find out what effects, good and/or bad, irinotecan eluting beads have on you and your liver metastasis from colorectal cancer. We do not know if you will benefit from this research study. It is possible that your condition will get better, but it is also possible that there will be no effect on your condition or that your condition will get worse. If you tumor is not confined to the liver only, it is possible that during this treatment you're tumor cells outside of the liver will grow despite this therapy. We can use what we learn from this research study to help other people with the same disease.

How many people will take part in this research study?

Up to 30 people will take part in this research study.

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

Before you begin the research study

You will need to have the following exams, tests or procedures to find out if you can be in the research study. These exams, tests, or procedures are part of regular cancer care and may be done even if you do not join the research 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 and physical examination by your study doctor
- Blood tests (about 2 tablespoons) to check your blood counts, kidney and liver function, tumor marker (CEA), and to evaluate how well your blood clots
- CT scan of the abdomen or MRI of the abdomen
    - A CT scan is a computerized x-ray that gives your study doctor pictures of the inside of your body
    - A MRI scan uses a magnetic field and radio waves to take pictures of the inside of your body
- Hepatic Angiogram
    - An angiogram is an X-ray test that uses a special dye and camera to take pictures of the blood flow in an arteries
- Pregnancy blood test (about 2 teaspoons) for women who are able to have children

During the research study

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

- Physical examination by your physicians will be performed before every treatment
- Blood tests (about 2 teaspoons) to check your blood counts, kidney and liver function will be done weekly while you are in the study
- Extra blood tests, including evaluation of the clotting ability of your blood, will be done every 3 weeks (about 2 teaspoons)
- Blood test for the tumor marker CEA (about 2 teaspoons) will be done after 2 treatments (6 – 8 weeks after study initiation)
- CT scan of the abdomen will be done 8 weeks after study initiation (after completion of two liver treatments)
- Patients who have cancer in 2 lobes of their liver will continue for 2 additional treatments if their follow up CT scan shows they are disease free

Prior to the injection procedure

- You will be asked to avoid any food intake the night before your scheduled procedure
- You may take your regular medicines with some water on the morning of the treatment
- Your doctor will review your medication list and inform you of any additional medicines that should be stopped before the treatment

During the injection procedure

The irinotecan eluting beads will be delivered directly to your liver under the guidance of x-ray images. This is done using a catheter which is placed into an artery in your groin area. The following steps will take place during the procedure:

- You will be treated with intravenous fluids, pain and anti-nausea medicines before the procedure will begin
- Your groin area will be cleaned and a needle will be placed into the artery in that area
- Once a guide wire is placed through the needle the needle will be removed
- Using x-ray equipment the guide wire will be moved towards the blood vessels around the liver
- X-ray dye will be used by your doctor to identify the correct location of the guide wire
- Imaging study for evaluation of the blood vessels of your liver, called a hepatic angiogram, will be done before injection of the irinotecan beads
- Once the tumor and its blood supply are identified the drug eluting beads will be delivered through a catheter placed over the guide wire

Following the injection procedure

Following the procedure you will be admitted to the hospital for a 24 hour observation. The following things may occur during your hospitalization:

- Any symptoms of nausea, vomiting and pain will be treated with medication
- About 2 tablespoons of blood will be collected following the test to evaluate your blood counts, kidney and liver function tests, electrolytes, and your clotting system
- You will be monitored for any side effect of the procedure

Possible use of a port

If the doctors or nurses cannot draw blood or give you medicine through your veins, you may be asked to have minor surgery to place an "indwelling catheter port" into a large vein in your chest. Medical staff will use the "port" to give you medicines and to draw blood. You will be asked to sign a separate consent form for this procedure, and the "port" will not be used unless you agree. If a port is necessary and you do not agree to its use, you may be unable to continue as part of the research study.

Study Chart

Another way to understand what will happen while you are participating in this clinical trial is by reviewing the Study Chart.

You will be treated with DEBIRI every 3 weeks in this research study. Two treatments, 3 weeks apart will be called a cycle. If your disease involves only one lobe of the liver that lobe will be treated. If your disease involves both lobes of the liver, the lobe with a larger amount of disease will be treated. Following two treatments or a cycle of treatment, a CT scan will be performed to see how your cancer has responded to treatment. This CT scan will be performed 8 weeks after the first treatment. In the case of a good response to the treatment, 2 more treatments will be given 3 weeks apart. The second cycle will be given to the previously treated lobe or the untreated lobe. The study chart below shows what will happen to you during Cycle 1 and future cycles. The left-hand column shows the day in the cycle and the right-hand column tells you what to do on that day.

Cycle 1

Day	**What you do**
Before starting study	• Your doctor will obtain medical history and perform a physical examination • Get routine blood tests, including blood counts, liver and kidney functions, and electrolytes (total of 2 tablespoons of blood)
Day before the study	• You must have nothing to eat or drink overnight prior to your treatment
Day 1 (the first day of DEBIRI treatment)	• You will receive intravenous medication for pain control, nausea control and antibiotic if needed • Following the procedure you will be admitted for observation for 24 hours
Day 2	• You will leave the hospital after your physician reviews your labs, this may be up to 24 hours after your treatment • Additional medication for pain and nausea control will be given to you to use at home as needed
Day 8 (1 week after first treatment)	• You will be seen by your physician, who will perform a physical exam • Get routine blood tests including blood counts, electrolytes, liver and kidney functions (total of 2 teaspoons of blood)
Day 15 (2 weeks after first treatment)	• You will be seen by your physician, who will perform a physical exam • Get routine blood tests including blood counts, electrolytes, liver and kidney functions (total of 2 teaspoons of blood)
Day 22	• You will be seen by your physician who will also perform a

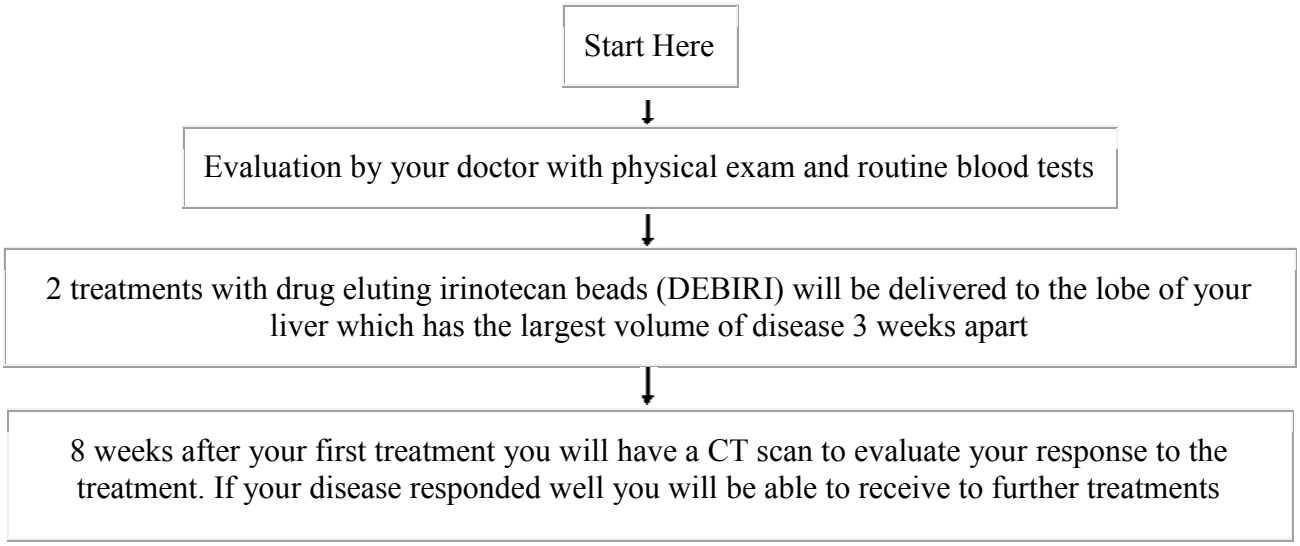
(3 weeks after first treatment, or the second day of DEBIRI treatment)	physical exam • Get routine blood tests including blood counts, electrolytes, liver and kidney functions (total of 2 teaspoons of blood) • You will receive intravenous medication for pain control, nausea control and antibiotic if needed • Following the procedure you will be admitted for observation for 24 hours
Day 29 (1 week after second treatment)	• You will be seen by your physician, who will perform a physical exam • Get routine blood tests including blood counts, electrolytes, liver and kidney functions (total of 2 teaspoons of blood)
Day 36 (2 weeks after second treatment)	• You will be seen by your physician, who will perform a physical exam • Get routine and tumor marker blood tests including blood counts, electrolytes, liver and kidney functions and CEA (total of 2 teaspoons of blood)
Day 57 (8 weeks after study initiation)	• 8 weeks after your initial treatment your CT scan will be done for evaluation of response to decide if you can have further treatments with irinotecan eluting beads

Future cycles

Day	**What you do**
Days 1-57	• If you had more than 1 lobe with cancer in your liver and your scans show a good response to the treatment, DEBIRI treatment will be repeated with a similar schedule (treatment every 3 weeks for a total of 2 treatments) • Physical exam by your doctor will be done prior to each treatment every cycle (more if your doctor tells you to) • Routine and tumor marker blood tests (total of 2 teaspoons of blood), including blood counts, electrolytes, liver and kidney function, will be done each week and you CEA level will be tested with your routine blood test closest to day 57. (These test may be more often if your doctor tells you to) • Get CT scans 8 weeks after you received 2 more DEBIRI treatments (you may require more scans if your doctor tells you so)
Following day 57	• Return to the clinic for your next exam and to discuss the results of the CT scan. If you respond well to the treatment your doctor will decide if further treatments should be done

Study Plan

Another way to find out what will happen to you during the research study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.



How long will you be in the research study?

You will be in the study for at least 8 weeks, and then for as long as your disease is responding to treatment and you are not having bad side effects.

Can you stop being in the research 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.

Can you be removed from this research study?

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

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

You may have side effects while on the research study. Everyone taking part in the research 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 stopped these treatments. In some cases, side effects can be serious, long lasting, or may never go away. Occasionally these interventions can result in complications which can carry the rare risk of death secondary to severe liver dysfunction or life threatening infection.

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

Risks and side effects related to **the injection of drug eluting irinotecan beads to the liver** include those which are:

Likely >20%

- Abdominal pain, mainly in your right upper abdomen
- Elevation of liver enzymes (the proteins made by the liver that are measured in the blood and indicate how well your liver is functioning)
    - Elevated liver enzymes which may cause no symptoms, or symptoms such as fatigue, weakness, you may bruise or bleed more easily, and you may have stomach pain or yellowing of the skin or eyes
- Nausea (feeling sick to your stomach) and vomiting (throwing up)
- Constipation (difficulty having a bowel movement)
- Fever
- Discomfort in your shoulder area
- Weakness
- Fatigue (feeling of being overly tired and lacking energy)
- Dehydration – loss of water in the body which can cause weakness, dry mouth, increased thirst, lightheadedness, dark urine and decreased urination requiring fluid infusion
- Decrease in appetite

Less Likely 5%-19%

- Decrease in the number of white blood cells (may make you more likely to get infections)
- Decrease in the number of platelets (may make you more likely to bruise or bleed)
- Decrease in the number of red blood cells (may cause you to feel fatigue or require blood transfusion)
- Hair loss
- Heart palpitations (unpleasant sensations of irregular and/or forceful beating of the heart)
- Increase in blood pressure (symptoms may include headache, dizziness, abnormal heart beat, blurred vision, ringing in the ears and nose bleeds)
- Shortness of breath
- Loss of appetite
- Depression - emotional state with extreme feelings of sadness, dejection, lack of worth, and emptiness
- Infection – requiring antibiotic treatment in the hospital or as an outpatient

Rare but Serious. < 5

- Pancreatitis, which can cause pain in the upper part of the abdomen, nausea and vomiting
- Cholecystitis (inflammation of your gall bladder, which may cause no symptoms or may cause burping, passing gas, inability to tolerate fatty foods, and feeling bloated and uncomfortable after eating)

- Gastritis (inflammation of your stomach which may cause abdominal discomfort, heart burn, difficulty eating and bleeding)
- Allergic reaction to the drugs used in the study to treat the cancer or any side effects (symptoms of an allergic reaction may include rash, hives, swelling, itching, flushing, changes in blood pressure, nausea, chest pain and shortness of breath)
- Non reversible liver damage, or rarely life threatening liver failure (you may notice yellowing of the skin and/or eyes; the liver failure may or may not be reversible)
- Serious life threatening infections
- Life threatening bleeding in your stomach or other gastrointestinal organs

Risks and side effects related to the **femoral artery puncture in the groin for delivery of the irinotecan beads** include those which are:

Likely >20%

- Pain at the catheter insertion site
- Bleeding or bruising at the catheter insertion site

Less Likely 5-19%

- Fainting
- Infection at the site of injection
- Significant amount of bleeding at the site of injection

Rare but Serious < 5%

- Clotting of the groin artery
- Allergy to the dye used in the procedure
    - Uncommonly, some people have allergic reactions (such as hives and itching) to the contrast agent
    - Serious reactions (for example, drop in blood pressure, difficulty breathing or severe allergic reaction and death) are rare
- Nerve damage
- Damage to blood vessels during the procedure requiring surgical repair
- Serious life threatening infections

Radiation Risks from Diagnostic Imaging

- It is unlikely that there will be any harmful effects from the radiation exposure you will receive from participating in this study.
- At high levels of exposure, scientists agree that radiation can cause cancer.
- At low exposure levels most scientists agree that the risk, if any, is very low. You will have low levels of radiation exposure with diagnostic imaging procedures.
- Risks from exposure to radiation may accumulate over a lifetime.

Blood Draw Risks

- Fainting
- Bleeding
- Bruising at the place on your arm where the blood was drawn or needle inserted
- Pain
- Swelling
- Infection (rare)

Reproductive Risks

- Study treatments may make you sterile (unable to have children).
- The drugs in this study and the delivery method may affect a baby, before or after the baby is born.
- You should not become pregnant or father a baby while on this research study because the drugs you take could possibly hurt an unborn baby.
- If you are pregnant now or if you are breast-feeding now, you may not take part in this research study.
- If you become pregnant while you are on the research study, you may not continue to take part in the research study.

For women who can become pregnant

- You should not become pregnant while you are in this study.
- You should not breast-feed your baby while taking drugs for this research study.

For men

- You should not make a woman pregnant while you are in this study.

For women and men

- If you are having sex that could lead to pregnancy, you should use birth control while you are in this study.
- Check with the study doctor about birth control methods and how long to use them
- Some methods might not be approved for use in this study.

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 injection of irinotecan eluting beads directly to your liver tumors 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 this type of treatment for liver metastasis from colon cancer. This information could help future cancer patients.

What other choices do you have if you do not take part in this research 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
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible

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

Will your 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.

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

- Fox Chase Cancer Center and affiliated Joint Centers, The Institutional Review Boards of The Fox Chase Cancer Center and Temple University, Temple University, Temple University Health system, Inc., and its affiliates or subsidiaries and other authorized representatives of these organizations.
- BTG PLC.
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people

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.

What are the costs?

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.

Even though it probably won't happen, it is possible that the manufacturer may not continue to provide the LC Bead which makes treatment with DEBIRI in this clinical trial possible. If this would occur, no one will be able to get more and the study would close.

If your insurance will not pay for medicines you may need to help with side effects, you may have to pay for them.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage . 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.

Will you be compensated?

You will not get paid for taking part in this research study.

What if you are injured while taking part in this research study?

If you are injured as a result of your participation in this research study, seek immediate medical care. Temple University Health System or its subsidiaries will treat the injury, though there is no commitment to provide monetary compensation or free medical care. Other financial compensation (such as lost wages or pain and suffering) for such injuries is not available.

What are your rights if you take part in this research study?

Taking part in this research study is your choice. You may choose either to take part or not to take part in the research 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.

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.

New findings

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

Who can answer your questions about the research study?

Important Contact Numbers	
If you are enrolled at the Fox Chase location (333 Cottman Ave)	
If you have questions about:	Please Call:
This study, including if you get sick or hurt	Dr. Dotan at 215-728-4300
If you have a concern or complaint	Risk Management Department at 215-728-2591
Your rights as a research participant on this study	FCCC Institutional Review Board at 215-214-3754
Your bills or health insurance coverage	Clinical Trial Financial Counselor at 215-214-3768
If you are enrolled at the Temple University location (3401 N Broad St)	
If you have questions about:	Please Call:
This study, including if you get sick or hurt	The Dr. Mittal at 215-707-2777
If you have a concern or complaint	Risk Management Department at 215-728-2591
Your rights as a research participant on this study	FCCC Institutional Review Board at 215-214-3754
Your bills or health insurance coverage	Social Work Department at 215-707-7569

Where can you 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 website at http://cancer.gov

- For NCI's clinical trials information, go to: http://cancer.govclinicaltrials/

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

By signing below, you tell us that you have gotten all of the information you need; that you have received clear answers to your questions, and that you agree to take part in the research study. You will receive a copy of this form. You may also request a copy of the research plan.

_____	_____	_____
Signature of Participant	**Print Name of Participant**	**Date**

By signing this form the Physician obtaining consent indicates that the research participant has been fully informed of all aspects of the research study.

_____	_____	_____
Signature of Physician Obtaining Consent	**Print Name of Physician Obtaining Consent**	**Date**

By signing this form the person obtaining consent indicates that the research participant has been fully informed of all aspects of the research study.

_____	_____	_____
Signature of Person Obtaining Consent	**Print Name of Person Obtaining Consent**	**Date**

_____	_____
Signature of Legally Authorized Representative (LAR)	**Date**

_____	_____
Print Name of LAR	**Relationship of LAR to Participant**

(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under the Commonwealth of Pennsylvania)

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AT TEMPLE UNIVERSITY HOSPITAL
All hospital services provided by Temple University Hospital

Authorization (Permission) to Use or Disclose (Release) Protected Health Information (PHI) for Research

IRB# and Protocol ID:	13-048
Study Title:	GI-063: Phase I study of drug-eluting irinotecan beads (DEBIRI) in refractory metastatic colorectal cancer with liver-only or liver-predominant disease
Principal Investigator:	Efrat Dotan, MD
Sponsor:	Dr. Efrat Dotan at Fox Chase Cancer Center, with support from Biocompatibles UK Ltd.

1. What is the purpose of this form?

This form is required by the Health Insurance Portability and Accountability Act of 1996. Specifically the privacy regulation (HIPAA) permits the research investigators listed above to use and disclose health information about you for the research study identified above which has been approved by the Fox Chase Cancer Center Institutional Review Board.

The sponsor is a person that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your protected health information for research. The elements of protected health information as defined by HIPAA are:

Data Elements for Protected Health Information (PHI)

- Names
- All geographic subdivisions smaller than a state (except for the first 3 digits of the zip code in some cases)
- All elements of dates (except year) for dates directly related to an individual (e.g., birth date, admission date, discharge date, date of death) and all ages over age 89 and dates indicative of that age
- Telephone numbers
- Fax numbers
- E-mail addresses
- Social security numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Device identifiers and serial numbers
- Web Universal Resource Locators (URL)

- Internet Protocol (IP) addresses
- Biometric identifiers, including finger and voice prints
- Full face photos and any comparable images
- Any other unique identifying number, characteristic, or code

2. What protected 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 research study, medical 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;
- Long-term information about your general health status and the status of your disease;
- Data that may be related to tissue, urine, and/or blood samples that may be collected from you.

You may request a blank copy of the data forms from the study doctor or his/her research staff to learn what information will be shared.

3. Why do the researchers want my protected health information?
Fox Chase Cancer Center will collect your protected health information and share it with the sponsor, as applicable, if you enter a research study. The centers will use your information in their cancer research study.

4. Who will be able to use my protected health information?
Fox Chase Cancer Center, Temple University, Temple University Health System affiliates, and Temple University Clinical Faculty Practice Plan 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. Fox Chase Cancer Center and Temple University may also permit these groups to come in to review your original records that are kept by Fox Chase Cancer Center so that they can monitor their research study.

- Dr. Efrat Dotan at Fox Chase Cancer Center
- Biocompatibles UK Ltd.
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law
- other people or organizations assisting with research efforts of the sponsor
- Central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed above

5. How will information about me be kept private??
The sponsor will keep all patient information private to the extent possible, even though the sponsor is not required to follow the federal privacy laws. Only researchers working with the sponsor will have access to your information. The sponsor will not release personal health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected. However, the laws of the Commonwealth of Pennsylvania or your state of residence may provide further privacy protection. However, the laws of the Commonwealth of Pennsylvania or your state of residence may provide further privacy protection.

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 specific research consent form.

Treatment by your physician will not be affected by whether you provide authorization for the requested use or disclosure except if your treatment is related to research.

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 protected 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 protected health information will be used for research. However, researchers may continue to use the protected 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 person below. He/she will make sure your written request to withdraw your permission is processed correctly.

Contact Name:	Efrat Dotan, MD
Contact Address:	333 Cottman Avenue Philadelphia, PA 19111
Contact Phone and FAX:	215-728-4300 and 215-728-3639

9. How long will this permission last?
If you agree by signing this form that researchers can use your protected 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 protected health information kept by Fox Chase Cancer Center and Temple University affiliates. However, while the research study is in progress, you may not be able to access your protected health information in order to preserve the integrity of the research. You will be able to access this information when the study is completed. You do not have the right to review and/or copy records kept by the sponsor or other researchers associated with the research study.

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

_____	_____	_____
Signature of Participant	**Print Name of Participant**	**Date**
_____	_____	_____
Signature of Person Obtaining Consent	**Print Name of Person Obtaining Consent**	**Date**

_____ _____
Signature of Legally Authorized Representative (LAR) **Date**

_____ _____
Print Name of LAR **Relationship of LAR to Participant**

(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under the Commonwealth of Pennsylvania)