Official Title:	NJ1105) Randomized Phase II Trial of Gemcitabine and Imatinib Mesylate versus Gemcitabine Alone in Patients with Previously Treated Locally Advanced or Metastatic Breast Cancer. A Study of The Cancer Institute of New Jersey Oncology Group (CINJOG)
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Consent for Participation in a Research Project
The Cancer Institute of New Jersey

Title of Study: (NJ 1105) Randomized Phase II Trial of Gemcitabine and Imatinib Mesylate versus Gemcitabine Alone in Patients with Previously Treated Locally Advanced or Metastatic Breast Cancer

Principal Investigator: [redacted]

This form is part of an informed consent process for a research study. It will give you information that will make it possible for you to decide whether you wish to volunteer for this research study. "Volunteer" means you want to take part; you do not have to. Once you understand what is involved and all of your questions have been answered, if you still wish to take part, you, along with the study doctor/principal investigator or a member of the study team, will be asked to sign this informed consent. You will receive a copy of the consent form to keep. If you have questions at any time during the research study you should feel free to ask them and obtain answers to your questions that you completely understand. You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Funding Company of Study
A pharmaceutical company [redacted]s a supporter of this research study. The study doctor is being paid to conduct this study according to a budget. The budget covers some of the costs of collecting the information, by th[redacted]equired by the study. [redacted]ill supply the drug imatinib mesylate. No other funding is provided b[redacted]

Financial Disclosure:
One of the investigators (a study doctor on the research team) participating in this study owns stock in one of the funding companies. Please feel free to ask any further questions you might have about this matter.

Why have I been asked to take part in this study?
You are being asked to take part in this study because you have locally advanced or metastatic (spread to

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You are being asked to take part in this study because you have locally advanced or metastatic (spread to other parts of the body) breast cancer. This type of cancer is usually treated with drugs called "chemotherapy" (drugs used to kill cancer cells). One common type of drug for this kind of cancer is called gemcitabine (also known as Gemzar®). [redacted] studies using gemcitabine with another drug called imatinib mesylate (also known as Gleevec®) with patients who had many different types of cancer. There is evidence that combined therapy (at least two different drugs) may be more effective than treatment with only one drug.
You are being asked to take part in this study, which evaluates gemcitabine alone compared to treatment adding imatinib mesylate along with treatment with gemcitabine to treat breast cancer. When you go on the study you will be randomized to one of the two treatments, either gemcitabine alone or gemcitabine and imatinib mesylate. Randomized means you have the same chance as a flip of a coin of receiving either treatment. You or your study doctor will not be able to pick which treatment you will receive.

Who may or may not take part in this study?
To be eligible for this trial, you may not have had more than two prior chemotherapy treatment regimens for your breast cancer such as you may not have had prior gemcitabine (gemzar) or imatinib mesylate (gleevec) before starting onto this study. You must have good function of your kidneys, liver and normal blood cell counts. If you are a female patient who is able to become pregnant and have a baby, you must have a negative pregnancy test, meaning you are not pregnant. You must agree to use adequate birth control (see the Pregnancy and Childbearing Precautions section of this consent).

If you have any of the following you may not be able to take part in this study:

- Any other cancer, unless completely treated for five years or more without it returning
- Tumors in your brain
- Any other serious disease or infection that would make it dangerous for you to take part in this study
- If you are receiving a blood thinner known as *warfarin* (also known as Coumadin)
- If you have been taking steroids (a type of hormonal substance) for a long time
- If you are not able to swallow pills

How long will the study take and how many subjects will take part?
This study is expected to last about 2-3 years. About 80 patients total are expected to take part, about 40 patients in each group. You will continue treatment until your disease worsens (progresses) or until you no longer are receiving benefit from the treatment. The study doctor will decide if the treatment is no longer of benefit for you and if you should come off of the study.

What will I be asked to do if I take part in this research study?
If you agree to take part in this study, you will have:

- A medical history and physical exam done by the study doctor prior to starting and every three weeks during the study.
- Blood tests prior to treatment and before every cycle of treatment during the study. This will include a complete blood count (CBC), chemistries and liver function tests.
- A CAT scan (computed axial imaging) or an MRI (Magnetic Resonance Imaging) may be done prior

to starting the study and every 6 weeks while you continue on the study. The CAT scan or MRI will be done to look at the size and location (place) of tumors.

- You will fill out a medication diary daily.
- If you are a woman who is able to become pregnant and have a baby, you will need to have a pregnancy test. If you are pregnant, you cannot take part.
- If you are a patient at [redacted] will also be asked to give blood samples for additional and future blood tests. These tests are optional. If you do not agree to these additional blood samples you may still take part in this study.
- Your weight will be taken
- Your doctor will determine how well you are able to do your daily routine, which is calculated as a number.
- You will also need to have an ECG (Electrocardiogram, also known as an "EKG" – a painless paper tracing of the heart's normal electrical activity).
- You will need to have an x-ray of your chest.
- If you are going to receive gemcitabine and imatinib mesylate treatment you will be asked to have biopsies (removal of small tissue sample from the area where your disease is) taken three times during your first cycle of treatment. If you are a patient at [redacted] hospital you have the option of traveling to [redacted] for biopsies performed at no cost to you. These biopsies may only be done [redacted] tissue samples are optional. If you do not agree to these additional biopsies you may still take part in this study.

The treatment schedule is as follows:

Gemcitabine Only:
A cycle is 21 days. The chemotherapy drug gemcitabine (Gemzar) will be given using a small needle or plastic tube into one of your veins. The dose (amount) of gemcitabine will be based upon your height and weight. Gemcitabine will be given on Days 3 and 10 of a 21 day (3 week) cycle. No drugs are given on Days 1-2, 4-9 or 11 through 21.

Gemcitabine Only Therapy

Days	1	2	3	4-9	10	11-21
Gemcitabine	No Drug Given		X	No Drug Given	X	No Drug Given
Blood Tests			X		X	1x between Days 15-17

For as long as you are receiving the above treatment, you will need to have blood tests done before gemcitabine is given. The blood will be taken from one of your veins using a small needle or plastic tube. The amount is equal to one (1) to three (3) teaspoons. The blood will be checked to see if you are having any side effects from the treatment.

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Gemcitabine/Imatinib Mesylate Combination:
A cycle is 21 days. The drug gemcitabine will be given using a small needle or plastic tube into one of your veins. The dose (amount) of gemcitabine will be based upon your height and weight. Gemcitabine will be given on Days 3 and 10 of a 21day (3 week) cycle.

Imatinib Mesylate (Gleevec) will be given as a standard dose (not according to height and weight). Imatinib mesylate will be taken on Days 1 to 5 and Days 8 to 12 orally (pill). No drugs are given on Days 6, 7, or 13 through 21. **You will need to be in a sitting position when taking the imatinib mesylate tablets and should take it with a large glass of water (1 cup). You should take imatinib mesylate with a meal if possible in the morning with breakfast. You understand you should not drink grapefruit juice or eat grapefruits while receiving this drug because grapefruit will interfere with the drug's absorption. Missed doses will not be made up.**

Combination Therapy

Days	1	2	3	4	5	6-7	8	9	10	11	12	13-14	15	16-21
Gemcitabine			X			No Drug Given			X			No Drug Given		No Drug Given
Imatinib	X	X	X	X	X		X	X	X	X	X			
Blood Tests	X								X				X	

For as long as you are receiving the above treatment, you will need to have blood tests done before gemcitabine is given. The blood will be taken from one of your veins using a small needle or plastic tube. The amount is equal to one (1) to three (3) teaspoons. The blood will be checked to see if you are having any side effects from the treatment.

You will need to have repeat CAT scans or MRI scan, depending on what your study doctor thinks is best for you. This will start after six (6) weeks of treatment, or more often if your doctor thinks it is necessary. These tests will be done to see how your tumor responds to treatment.

If your tumor starts to grow, this treatment will be stopped and other treatments will be considered. If you have severe (very bad) side effects, this treatment will be stopped and other treatments will be considered. If your treatment is stopped for something serious, like a bad reaction, you will be followed every three (3) months with a CAT scan or MRI and blood tests until your disease starts to get worse. You will also be followed for an update of your disease every 3 months. This will be done either by telephone or when you come in for a routine visit, which you would have as part of your standard care after you stop taking part in this study. You may continue treatment as long as your disease does not worsen.

PLEASE NOTE: THERE IS NO PLACEBO (INACTIVE DRUG, OR "SUGAR" PILL) USED IN THIS STUDY. ALL PATIENTS WILL RECEIVE AN ACTUAL DRUG.
A table of tests and procedures done during the study is presented at the end of this consent.

What are the risks and/or discomforts if I choose to take part in this 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 drugs. In some cases, side effects can be serious, long lasting, or may never go away. Any risks listed may be serious enough to result in hospitalization and/or death.

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

The following are side effects, which may occur with the drug gemcitabine (Gemzar®):

Common Side Effects:

- A lowered number of red blood cells. This is a condition called anemia. It may make you feel very tired and/or short of breath.
- A lowered number of white blood cells. This may make it more likely for you to get an infection.
- A lowered number of platelet cells. This may make it more likely for you to bleed or bruise ("black and blue" marks).
- Rash
- Nausea (a "sick" feeling in the stomach) and vomiting. Nausea is rarely severe (less than one patient in 100 had severe nausea and vomiting). The symptoms are easily managed with standard medication.
- Blood tests may show that your liver is not working the way it should. This is usually mild and generally does not stop treatment.
- Cough
- Fatigue – a very tired feeling
- Flu-like symptoms. These include fever, headache, backache, muscle soreness, no appetite (not feeling like eating), fatigue and chills. This happens in about 20 out of 100 patients, usually for about a day or so after receiving chemotherapy. The symptoms are treated with ibuprofen (Motrin, Advil) and diphendydramine (Benadryl).
- Swelling of the legs and feet.
- Some cases of swelling of the face have also been reported. This is usually mild to moderate, rarely severe, sometimes is painful, and stops after completing treatment with gemcitabine.

Less Common or Rare Side Effects:

- Allergic reaction with difficulty breathing and wheezing after receiving the drug has been reported in less than one (1) of 100 patients. It is usually mild and goes away, but treatment with IV (intravenous) medications may be needed.
- Shortness of breath that does not eventually stop is seen rarely; if this happens, you must report this to your study doctor right away.
- Inflammation of the lung is seen rarely. However, this type of pneumonia is very rarely fatal (does not usually cause death). Always notify your study doctor if you have a cough or shortness of

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breath.

The following are side effects, which may happen with the drug imatinib mesylate (Gleevec®):

Likely:

- Decrease in the number of some white blood cells (neutrophils/granulocytes), which may lead to an increased risk of infection
- Fatigue
- Rash; flaking of skin
- Diarrhea
- Nausea and vomiting
- Swelling in the arms and legs
- Collection of fluid between the thin layers of tissue lining the lung and the wall of the chest cavity
- Anemia or decrease in a red blood cell protein (hemoglobin) that carries oxygen in the body
- Pain in your abdomen

Less likely:

- Allergic reaction
- Fluid in the sac around the heart
- Fever
- Chills and shivering
- Sweating
- Weight gain
- Hair loss
- Changes in skin color
- Itching
- Severe skin and gut lining reaction that may include rash or death of tissue
- Loss of appetite
- Fluid collection in the abdomen
- Constipation
- Dehydration
- Gassiness
- Heartburn
- Irritation or sores
- Changes in taste
- Bleeding in the brain
- Bleeding from the gastrointestinal tract (e.g., the stomach or intestines)
- Bleeding inside the tumor
- Infection
- Swelling in the head and neck
- Abnormal liver or bone enzyme levels

- Abnormal level of bilirubin in the blood. Bilirubin is a bile pigment found in the liver.
- Increased level of creatinine in the blood. Creatinine is a substance normally eliminated by the kidneys into the urine.
- Decreased levels of potassium, sodium and /or phosphates in your blood.
- Arthritis
- Destruction or death of bone
- Dizziness
- Abnormal changes in brain function
- The abnormal buildup of cerebrospinal fluid in the brain
- Anxiety
- Weakness or loss of function caused by damage to nerves
- Condition of the nervous system that causes numbness, tingling, burning
- Swelling of the nerve in the back of the eye that is responsible for vision
- Watery eyes
- Pain in your back, chest and/or lungs, head, throat, and joints
- Cough
- Shortness of breath
- Swelling around the lungs
- Kidney failure
- Flu-like symptoms
- Formation or presence of a blood clot inside a blood vessel
- Decreased number of a type of white blood cell (lymphocyte)
- Muscle cramps
- Swelling of the outer layers of an organ
- Decreased number of blood cells (platelets) that help to clot blood

Rare but serious:

- Decrease in heart's ability to pump blood
- Scarring of the lungs that can affect your ability to breathe and may make you short of breath

Side Effects of having blood drawn from a vein or IV (intravenous) therapy: When your blood is drawn, there is a possibility that there may be a bruise ("black and blue" mark), bleeding or infection (rarely) at the place where the needle entered your vein.

Pregnancy and Childbearing Precautions:

If you are a woman who is able to become pregnant and have a baby and are sexually active with men, you must agree to not become pregnant during the time you are taking part in this study because it is not known what effects this treatment may have on a developing baby. If you are a sexually active man, you must take adequate precautions to avoid getting a woman pregnant since it is not known what effects this treatment may have on sperm cells (the cells which fertilize a female egg). If you are not willing to use adequate birth control, you must not sign up for this study. Adequate birth control includes: a diaphragm with cream to kill

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sperm cells, an intrauterine device ("IUD"), latex condoms, a tubal ligation for a woman (having your "tubes tied") or a vasectomy for a man.
Your cancer is a type of cancer with a high risk of developing blood clots. Hormonal birth control also increases your risk of developing blood clots. It is recommended that while you are on-study you do not use hormonal birth control (birth control pills or implantable birth control).

You must not breast feed a baby while taking part in this study, because the effects of this treatment on a baby cannot be determined.

If you become pregnant, you must immediately tell the study doctor, and you will stop study therapy.

Taking Other Drugs:
Imatinib may change the way other drugs work in your body, or other drugs may change the way imatinib is used in your body. Therefore, do not take any over-the-counter medicines, especially Tylenol® (acetaminophen) or products containing Tylenol®, any herbal or "natural" products, vitamins, food supplements or any other types of special products while taking part in this study, unless you tell your study doctor and permission is given for you to continue to take these medications.

You must not be receiving:
- **Warfarin (Coumadin) or,**
- **Any oral (by mouth) steroid (Decadron, Prednisone, Medrol) daily.**

There are drugs that you will not be allowed to take while on the study your study doctor will discuss these with you. You must tell your study doctor about any medicines any other doctor or dentist has prescribed.

Are there any benefits if I choose to take part in this research study?
The benefits of taking part in this study may be that your cancer may shrink or stay the same size for a long period of time. However, you may receive no direct benefit from taking part in this study.

What are my alternatives if I don't want to take part in this study?
You have the following other choices:
- Gemcitabine alone, without being on-study;
- Other chemotherapy drugs used to treat this disease;
- You may choose to have no treatment, except care to make you more comfortable.

How will I know if there is information learned that may effect my willingness to take part in this research study?
During the course of the study you will be updated about any new information that may affect your willingness to remain in the study. If new information is learned that may affect you after the study has completed, you will be contacted.

Who will have access to my research records from this study?

By taking part in this study, you should understand that we will be collecting your personal health information. This includes, but is not limited to, demographic data (name, date of birth, etc.) and data on your health (your history, physical findings, laboratory results, study related finding etc.). During the course of the trial, study visitors (known as monitors) will review your medical and research record to verify we collected your study information properly. These monitors are either hired or employed by the sponsor. Sometimes, they will need to take notes or photocopy parts of your medical record. We will replace your name on these pages with your assigned study number. This data will be reported to The Office of Human Research Services (OHRS) on a regular basis, as required by the study. OHRS will analyze, process and store your data with electronic data processing systems. The authorization for use of your research data has no expiration date and may be subject to redisclosure by OHRS and no longer be protected. Your personal identity however, that is your name, address, and other identifiers, will remain confidential (a study number will be used for your name). Only the study doctor, research team and study monitor will be able to link the study number to your name. Your data may also be forwarded to domestic and foreign drug regulatory agencies if you have an adverse (bad) reaction.

The following groups of people may also be allowed to inspect sections of your medical and research records related to this study:

- [redacted]

Your data may also be submitted to domestic and foreign drug regulatory agencies in applications for marketing authorization and may be used in scientific publications. If the findings from the study are published, you will not be identified by name. Your identity will remain confidential (private) unless the law requires disclosure such as reporting individuals with communicable diseases (those diseases that are passed from person to person). In this case, you will be informed of the intent to disclose (give out) such information to the authorized state agency. Such a law has already existed in New Jersey for several years.

You have the right to access your personal data at your study doctor's office and to request corrections of any of your personal data that are wrong.

Will there be any costs to me to take part in this study?

[redacted] will supply the drug imatinib mesylate. Imatinib mesylate is provided free of charge by Novartis Pharmaceuticals for a time span of one year or as long as you remain on study and are

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responding to treatment. If you are no longer responding to treatment you may only be able to continue imatinib mesylate outside of this study. This would be at your own expense if alternative means of obtaining imatinib mesylate (such as through your insurance) were not available. The issue of cost and payment outside of this study will be discussed with you or you will be referred to a financial counselor.

Gemcitabine is a standard (usual) treatment for this cancer. You or your insurance company will be billed for the cost of this treatment. Whatever costs your insurance company does not pay will be your responsibility. Laboratory work and imaging studies (CT Scan or MRI) are part of the standard treatment and will be billed to you or your insurance company because these tests would be done if you choose not to be a part of this study.

Will I be paid to take part in this study?
You will not be paid to take part in this study.

What will happen if I become injured during the study?
If you take part in this study, you will be exposed to certain risks of physical injury in addition to those connected with standard forms of therapy. Please refer to Risks/Discomforts section. Medical and/or dental treatment will be arranged by [redacted] who sustain physical injuries or illnesses as a direct consequence of taking part in this research. Your health insurance carrier or other third party payor will be billed for the cost of this treatment. No additional financial payment is available. You are not giving up any of your legal rights by signing this form or by taking part in this research study.
[redacted] ot provide payment for any medical expenses, which you may incur as a result of your participation in this study. [redacted] de no other type of compensation.

What will happen if I do not wish to take part or decide not to continue in the study?
You may choose not to be in the study and if you do choose to take part, it is voluntary. You may also refuse to take part, or change your mind at any time. If you do not want to enter the study or decide to withdraw (stop taking part) from the study, your relationship with the study staff will not change, and you may do so without penalty or loss of benefits to which you are otherwise entitled. If you do not want us to continue using the data we have already collected about you, you must withdraw your permission in writing. Even if you withdraw your permission to use the data about you, we cannot retrieve (get back) any of the information previously submitted. The Food and Drug Administration require us, however, to continue to report anything that relates to the safety of these drugs.

At any time, the study doctor can decide to withdraw you from this study (take you off study) because further participation would not be in your best interest. Your study doctor can stop treatment even if you are willing to continue. If you, or your study doctor, decide to withdraw you from the study you may be asked to return for a final visit for safety reasons, or to return study medication.

Also, you should understand that the study doctor or [redacted] in consultation with the Principal Investigator, can withdraw you from the study at any time if you do not follow the instructions related to the study, or if you need a different treatment.

Who may I contact if I have any questions?

If you have any questions about your participation in this study, you can contact the study doctor:

[redacted]

If you have any questions about your rights as a research subject, you can contact:

[redacted] Review Board

[redacted]

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

You have the right to ask questions concerning any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and receive answers to all of your questions.

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions regarding this form or this study have been answered. I agree to take part in this research study and have been given a copy of this consent.

Patient Name: _____

Patient Signature: _____ Date:_____

Text continued on next page

ADDITIONAL RESEARCH TESTING, FUTURE USE BLOOD/TISSUE SAMPLES OR THE INTENT TO STORE SAMPLES:

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If you do not want your samples used for additional research testing, future research or for genetic testing (testing of any leftover tissue to determine if some tissue is more at risk for certain diseases), this will not affect your ability to take part in this study or in future studies.

Please initial each one of the following sentences that applies:

_____I agree to be contacted by the Investigators for future research studies.

_____I **do not** agree to be contacted by the Investigators for future research studies.

_____ I agree to the use of my blood/tissue for additional research testing, future research or genetic testing.

_____ I **do not** agree to the use of my blood/tissue for additional research testing, future research or genetic testing.

What do I do if I do not want my samples to be used?

[redacted] may keep records linking your identity with your blood/tissue sample(s) forever. You can ask that your blood/tissue sample(s) and materials obtained from your sample(s) be destroyed. In such case, you should notify the study doctor in writing that you wish to have your sample(s) destroyed, and any materials obtained from your sample(s), destroyed. [redacted] will destroy any of your sample(s) that are still available after your request is received.

How will my information be kept private and confidential?

Information obtained from material obtained from your sample(s) will be kept confidential so that only Dr. [redacted] will be able to link your individual research results with your identity.

Your sample(s), and materials derived from your sample(s), will be given a code number, and stored in a password protected secured database. These password-protected databases are located on secured servers with limited access by key study personnel. Only information related to your diagnosis will be linked with the sample's code number. Your name, date of birth, address, or other personal identifying information, will not be linked with the sample(s) you give.

This basic research is not intended to give you clinical information. You understand and agree that you will not be told about your individual research results. Information resulting from this research will not be entered into your medical record. Neither you, nor your family members, nor outside parties or study doctor will be allowed to look at your individual research results. It is possible, however, that members of regulatory authorities, such as the U.S. Food and Drug Administration, UMDNJ Institutional Review Board, or other persons required by law may be allowed to look at this information. Because we are not sure of the significance of the laboratory research, we will not use those results to manage your medical care.

What are my rights if I agree to the use of my blood/tissue for other types of research or for genetic testing for future research?

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You understand that you have the right to ask questions about your blood/tissue samples at any time.

I agree to the use of my blood/tissue for other types of research or for genetic testing for future research.

Patient Name: _____

Patient Signature: _____ Date:_____

SIGNATURE OF READER/TRANSLATOR IF THE SUBJECT DOES NOT READ ENGLISH
The person who has signed above, _____, does not read English well. I read English well and am fluent in _____, a language the patient understands well. I understand the content of this consent form and have translated for the patient the entire content of this form. To the best of my knowledge, the patient understands the content of this form and has had an opportunity to ask questions regarding the consent form and the study, and these questions have been answered.

Reader/ Translator: Name: _____

Signature: _____ Date: _____

Witness: Name: _____

Signature: _____ Date: _____

SIGNATURE OF INVESTIGATOR OR RESPONSIBLE INDIVIDUAL
To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the patient have been accurately answered and the patient has been given a copy of the consent.

Name of Investigator/Person Obtaining Consent: _____

Signature: _____ Date: _____

Table of Study Tests and Procedures

Tests and Procedures	Pre-study	Weekly	Prior to Each Cycle	Every 2 Cycles	Off Treatment	Follow-up
Informed consent	x					
History, physical and height	x		x		x	
Weight and vital signs	x		x		x	
Blood tests	x	x	x		x	
Review of side effects			x[4]		x	
EKG and chest x-ray	x					
Pregnancy test[1]	x					
Disease Assessment[2]	x			x		x[5]
Medication Diary[3]			x			
Update of disease status						x[5]
Optional Future Use Samples	x[6]					
Optional Biopsies	x[7]					

[1] Women able to get pregnant must have a negative pregnancy test within 1 week of starting the study.
[2] If your disease responds to treatment a review of your disease will be repeated as often as you doctor feels is necessary. This will be done by repeating CAT or MRI scans or any other method the study doctor may feel is needed.
[3] Medication is to be filled out daily in the diary by the patient and reviewed with the research nurse at every clinic visit.
[4] Patient will be asked and checked for side effects of receiving treatment. This will be done at each visit. If the patient is not scheduled for a visit this information can be taken over the phone.
[5] Patients disease will be followed with imaging scans or tumor measurements every 3 months until their disease gets worse. Patients will also be followed for an update of their disease every 3 months. A telephone call may be made for disease update information.
[6] Optional blood samples taken from [redacted] only.
[7] Optional samples taken for patients in the combination group, an attempt will be made to obtain tissue during Cycle 1, before the start of treatment on Day 1, before treatment on Day 3, and after treatment on Day 10. C[redacted] patients or patients willing to travel to [redacted]