



Heartland
Cancer Research

An NCI-Designated Community
Clinical Oncology Program

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INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**TITLE OF STUDY: CALGB 90601 A RANDOMIZED DOUBLE-BLINDED PHASE III STUDY
COMPARING GEMCITABINE, CISPLATIN, AND BEVACIZUMAB (IND #7921, NSC #704865) TO
GEMCITABINE, CISPLATIN, AND PLACEBO IN PATIENTS WITH ADVANCED TRANSITIONAL CELL
CARCINOMA**

PRINCIPAL INVESTIGATOR: Alan P. Lyss, M.D.

PARTICIPANT NAME: _____

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

You are being asked to take part in this study because you have advanced transitional cell cancer of the urinary tract.

Why is this study being done?

The purpose of this study is to compare the effects, good and/or bad, of the combination of the chemotherapy drugs gemcitabine and cisplatin (chemotherapy) with the combination of gemcitabine, cisplatin, and the experimental drug bevacizumab on you and your transitional cell cancer to find out which is better. Bevacizumab is an antibody that can block a protein called "vascular endothelial growth factor" (VEGF), and can slow the growth of new blood vessels in the tumor. Bevacizumab (also called Avastin) has been approved by the Food and Drug Administration (FDA) for the treatment of advanced colon cancer, lung cancer and glioblastoma (a type of brain cancer). Bevacizumab is also approved for the treatment of advanced kidney cancer in combination with interferon. The FDA recently recommended removal of bevacizumab's approval for the treatment of metastatic breast cancer, however, bevacizumab continues to be used in other investigational research studies for both metastatic and earlier stage

breast cancer. Bevacizumab used in combination with everolimus in this study of advanced kidney cancer should be considered experimental.

The combination of gemcitabine and cisplatin is one commonly used treatment that has been shown to make some patients with transitional cell carcinoma live longer. This research is being done to see if adding bevacizumab to gemcitabine and cisplatin will delay the growth of your cancer and allow you to live longer.

How Many People Will Take Part in the Study?

About 500 patients will take part in this study.

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

Before you begin the study . . .

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

- Medical history and physical examination;
- Blood tests, liver function tests, urinalysis, and pregnancy test if applicable or if of child-bearing potential;
- EKG, CAT or MRI scan, and bone scan.

If the exams, tests and procedures show that you can be in the study and you choose to take part, then you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your doctor will choose or know the group you will be in. You will have an equal chance of being placed in either group. The two treatment groups are:

Arm A: Gemcitabine, cisplatin, and placebo (sugar water or salt water)

Arm B: Gemcitabine, cisplatin, and bevacizumab (an experimental drug)

The placebo is given in Arm A so that patients in both groups receive similar-looking treatments. That means all patients get gemcitabine and cisplatin by vein (IV), followed by another infusion through the same vein that will contain either bevacizumab or placebo. This way, neither you nor your doctor can tell which group or arm you are in, and that makes the study more objective.

Even after you have completed study treatment, you and doctor will not be told which treatment you received. However, in case of an emergency, your doctor may be able to find out whether you are getting the bevacizumab or the placebo. If this happens, you will be required to drop out of the study.



During the study . . .

Each treatment group will receive treatment over 3 weeks. This 3-week period is called "a cycle." Regardless of which treatment group you are in, you will receive treatment on the following schedule:

Study Schedule

	Week 1	Week 2	Week 3		
Gemcitabine	X	X	Rest	Repeated a total of 6 times, then:	Bevacizumab/placebo only, every 3 weeks.
Cisplatin	X	*	Rest		
Bevacizumab/placebo	X		Rest		

* Depending on your kidney function, you may receive cisplatin on this day, also.

With each cycle, you will be given anti-nausea medicines by your doctor to help decrease the side effects of the treatment. On Day 1 of every cycle, you will receive gemcitabine as an infusion (through a vein in your arm). You will also receive fluids through a vein in your arm, followed by cisplatin as an infusion through a vein in your arm. After that, you may receive additional fluids through a vein in your arm at the choice of your doctor. You will always receive the chemotherapy for the first 6 cycles before the bevacizumab/placebo.

Your first dose of bevacizumab/placebo will be given on Day 1 of the first cycle over 90 minutes. Later infusions of bevacizumab/placebo may be given over a shorter time interval, depending on how you tolerate the infusions.

You will return one week later for an infusion of gemcitabine (through a vein in your arm). Your doctor will check a blood count before giving you treatment, and may modify the treatment plan for the day based on results of the blood test. You may also receive anti-nausea medicines before receiving gemcitabine.

Your doctor will prescribe anti-nausea medicines to take at home to prevent nausea and vomiting.

Tests and Procedures:

During the time that you are receiving the study treatment, you will need the following tests and procedures. They are part of regular cancer care.

- physical examinations (every 3 weeks)
- blood tests, including chemistries (every 3 weeks) and blood counts (2 weeks out of 3)
- liver function tests (every 3 weeks)
- CT or MRI scans, and/or bone scans to monitor your disease

You will also have urine tests every 3 weeks. These are often part of standard cancer care, but it is possible that these tests might be done more frequently since you are in this study.

Your doctor may decide to continue your treatment with chemotherapy for between four and five months, and the bevacizumab or placebo as long as the tumor does not grow and you are able to tolerate the treatment.

When I am finished taking the study treatment:

After you have finished receiving the study treatment, you will be asked to have physical examinations and scans to monitor your disease every 3 months for up to 7 years after you started the study.

How Long Will I be in the Study?

The study treatment will be continued for as long as your urinary tract cancer is responding to or is stabilized by the drugs and you do not have any severe side effects from the drugs. If your cancer is not growing but you develop severe side effects from the chemotherapy, your doctor may ask you to continue the bevacizumab/placebo without the gemcitabine and cisplatin.

If your cancer worsens, you will be removed from the study. In this event, you and your doctor will not be told which treatment you received. Whether or not you remain on study treatment, the study doctor will continue to follow your progress for up to seven years.

Can I stop being in the study?

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

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

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

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

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the drugs. In some cases, side effects can be serious, long lasting, or may never go away, or may cause death.

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

Risks and side effects related to the therapy we are studying include:

Arm A (Gemcitabine, cisplatin, and placebo)

LIKELY:

- Nausea
- Vomiting, which can lead to dehydration
- Changes in blood chemistry like potassium and magnesium
- Loss of appetite
- Flu-like syndrome, which includes fever, chills, and/or fatigue
- Lowered white blood cell count that may lead to an increased risk of infection
- Lowered platelet count that may lead to increased bruising or bleeding
- Lowered red blood cell count that may cause tiredness or shortness of breath (if the counts get too low, you may need a transfusion)

LESS LIKELY:

- Hair loss
- Diarrhea
- Constipation
- Nerve damage causing tingling, numbness and/or weakness in the hands or feet
- Loss of reflexes
- Rash
- Hearing loss
- Decreased kidney function
- Abnormal liver function tests or decreasing liver function
- Small amount of blood or protein in the urine
- Cough or wheezing or shortness of breath

RARE BUT SERIOUS:

- Blood disorder leading to decreased kidney function and anemia (hemolytic uremic syndrome)
- Kidney failure
- Severe allergic reaction (life-threatening breathing problems)
- Another cancer called acute leukemia
- Acute Respiratory Distress Syndrome (lung damage that could be fatal)

Arm B (Gemcitabine, cisplatin, and bevacizumab)

LIKELY:

- Nausea
- Vomiting, which can lead to dehydration
- Changes in blood chemistry like potassium and magnesium
- Loss of appetite
- Flu-like syndrome, which may cause fever, chills, fatigue, and aches and pains
- High blood pressure
- Lowered platelet count that may lead to increased bruising or bleeding

- Lowered red blood cell count that may cause tiredness or shortness of breath (if the counts get too low, you may need a transfusion)
- Lowered white blood cell count that may lead to an increased risk of infection. Neutropenia (lowered white blood cell count) is a common side effect of chemotherapy drugs. This may happen more often when bevacizumab is added to chemotherapy. In some studies of bevacizumab plus chemotherapy, there was also an increase in fever with neutropenia and infections. Rarely, these infections resulted in death.

LESS LIKELY:

- Nosebleed
- Itching
- Reactions while drugs are being given such as fever, chills, or nausea, which can be severe.
- Hair loss
- Constipation
- Diarrhea
- Rash or hives
- Fatigue
- Dizziness or fainting
- Cough, hoarseness, runny or stuffy nose
- Shortness of breath
- Abdominal pain
- Hearing loss
- Nerve damage causing tingling, numbness and/or weakness in the hands or feet
- Loss of reflexes
- Kidney damage
- Abnormal liver function as seen on a blood test: ALT, AST, alkaline phosphatase, bilirubin
- Protein in urine, which may be a sign of kidney damage and could lead to kidney failure
- Blood in the urine
- Bleeding in the stomach or intestine
- Blockage of the intestine with severe constipation
- Blockage of the stomach or intestine
- Wound healing problems
- Blood clots in the legs, lungs, or in your abdomen
- Vaginal bleeding
- Irritation of the bowels
- Heartburn
- Sores in the mouth or throat
- Aches in various body parts including the chest, joints, or muscles
- Headache
- Allergic reactions
- Abscess (a type of infection) around the rectum
- Weight loss
- Abnormal heart rhythm (which may be serious)

- Increased blood level of a protein (troponin 1) indicating damage to the heart muscle
- Abnormal test of bone health: alkaline phosphatase
- Damage to the jawbone that may be painful and might require surgery to remove the damaged area. Rarely, the damage could be permanent. This might be more likely to occur if you also take a medicine in the group called "bisphosphonates."

RARE BUT SERIOUS:

- Stroke
- Transient ischemic attack (mini-stroke)
- Heart attack
- Chest pain (angina)
- Blood clots in the kidney that can lead to anemia, bleeding, or kidney failure
- Kidney failure
- Another cancer called acute leukemia
- Stomach and or other gastrointestinal ulcers
- Bowel perforation and bowel anastomotic dehiscence: Bowel perforation occurs when an opening exists in the bowel wall allowing bowel contents to spill into the abdomen. Bowel anastomotic dehiscence is a breakdown in the surgical connection between two pieces of bowel. These events can be life-threatening. You should inform your doctors if you experience symptoms suggestive of bowel perforation, such as worsening or new pain in the abdomen or the rectum.
- Perforation in other places in the body including the nose
- Fistula: An abnormal (not usually present) connection between organs in the body. Fistula formation may lead to life-threatening complications including serious infections, bleeding or dysfunction of the organs.
- Severe or life-threatening internal or external uncontrolled bleeding, such as in the brain or lung
- Severe allergic reaction that can mean difficulty breathing, drop in blood pressure, or loss of consciousness
- Decrease in heart function or heart failure
- Inflammation of the lungs, which would result in shortness of breath or cough
- Acute Respiratory Distress Syndrome (lung damage that could be fatal)
- Reversible Posterior Leukoencephalopathy Syndrome (RPLS) or similar leukoencephalopathy syndrome: RPLS is a medical condition related to leakiness of blood vessels in the brain and can cause confusion, blindness or vision changes, seizure, and other symptoms, as well as changes in brain scans. This condition is usually reversible, but in rare cases, it is potentially life-threatening or fatal and may have long-term effects on brain function.

Unanticipated side effects may occur which have not been reported. If you have any unusual symptoms, report them immediately to your doctor.

Reproductive risks: Loss of function of the ovaries, that can lead to menopause. The effect of this on fertility is not known.

You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while receiving study treatment and for at least 3 months after completing or discontinuing study treatment. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.

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 adding bevacizumab to gemcitabine and cisplatin will be more useful against cancer compared to gemcitabine and cisplatin alone, there is no proof of this yet. We do know that the information from this study will help doctors learn more about these drugs as a treatment for cancer. This information could help future cancer patients.

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

Your other choices may include:

- Getting treatment or care for your cancer without being in a study, which may involve using some of the same, or different drugs
- 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 my medical information be kept private?

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

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

- The Cancer and Leukemia Group B (CALGB)
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- Genentech pharmaceutical company, the makers of bevacizumab (Avastin®).
- Missouri Baptist Medical Center Staff
- Missouri Baptist Institutional Review Board (a group of people who review the research study to protect your rights)

The CALGB has received a Certificate of Confidentiality from the federal government, which will help us to protect your privacy. The Certificate protects against the involuntary release of information about you collected during the course of the study. The researchers involved in this project may not be forced to identify you in any legal proceedings (criminal, civil, administrative, or legislative) at the federal, state, or local level. However, some information may be required by the Federal Food, Drug, and Cosmetic Act, the U.S. Department of Health and Human Services, or for purposes of program review or audit. Also, you may choose to voluntarily disclose the protected information under certain circumstances. For example, if you or your guardian requests the release of information about you in writing (through, for example, a written request to release medical records to an insurance company), the Certificate does not protect against that voluntary disclosure.

What are the costs of taking part in this study?

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

The NCI is supplying the bevacizumab/placebo at no cost to you. However, you or your health plan may need to pay for costs of the supplies and personnel who give you the bevacizumab/placebo. The cost of the cisplatin and gemcitabine will be charged to you/your insurance company.

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

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

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

It is important that you tell your study doctor, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her.

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

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

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

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

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

It may be necessary to contact you at a future date regarding new information about the treatment you have received. For this reason, we ask that you notify the institution where you received treatment on this study of any changes in address. If you move, please provide your new address to the following person:

Jean Roark, CCOP Administrator
3015 N. Ballas Road
St. Louis, Mo. 63131
314-996-5569

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

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study.

For questions about your rights while taking part in this study, call the Missouri Baptist Medical Center Institutional Review Board (a group of people who review the research to protect your rights) You can contact Barb Woodson at 314-996-5186.

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

Related Studies

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

The results of these research studies will not be provided to you or your doctor, nor will the results have any effect on your treatment. It is unlikely that what we learn from these studies will have a direct benefit to you. However, the information learned from these studies may benefit other patients in the future.

The results from these studies may be published, but individual patients will not be identified in these publications.

There will be no charge to you for participating in these research studies. Your sample will only be used for research and will not be sold. The research done with your sample may help to develop new products in the future.

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

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

If you decide now to participate and then change your mind at any time about participating in these studies for any reason, you should contact your institution and let them know that you do not want the researchers to use your sample. The sample will then no longer be used for research. It will either be destroyed or returned to your institution for storage. The sample will also be returned to your institution upon request if needed for any other medical or legal reasons.

You can say “yes” or “no” to each of the following studies. Please mark your choice for each study. No matter what you decide to do, it will not affect your care.

Studies on tissue and blood:

As part of this research study, we would like to request your permission to study cells from your tumor. The tumor samples were previously obtained when your disease was first diagnosed or when you had surgery. These tumor samples will be used in a laboratory to investigate bladder cancer.

The researchers would like to keep some of the tissue that was left over for future research. If you agree, this tissue will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How is Tissue Used for Research" to learn more about tissue research. [This NCI information sheet is available at <http://www.cancerdiagnosis.nci.nih.gov/specimens/patient.html>]

In addition, the researchers would also like to collect additional samples of your blood. The researchers would like to investigate whether substances in your blood (sometimes called tumor markers) are related to the way that your body responds or doesn't respond to the chemotherapy you receive in this trial. Approximately 8 teaspoons of additional blood would be collected at the beginning of the study, after 9 weeks of therapy, after the end of your treatment, and at the end of the study.

Finally, researchers will try to learn if smoking affects the way your body responds to treatment. If you agree to the additional study, we would also like to ask you about your smoking history. This questionnaire should take about 10 to 15 minutes to complete and will be done at your first clinic visit and after about 3 months of study treatment.

1) I agree that my specimens may be used for the research described above.

_____ Yes _____ No Initials _____

Genetic studies on blood cells:

The researchers would like to investigate whether substances in your blood are related to the way that your body responds (or doesn't respond) to the chemotherapy you receive in this trial. These tumor markers are inherited through your family, and could be passed to your children. These are also called genetic studies.

Blood taken before treatment will be used to learn how certain genes influence the effectiveness and side effects of gemcitabine, cisplatin, and bevacizumab. In order to study the genes the DNA must be removed from your blood sample. DNA is the substance that makes up your genes. Genes are the units of inheritance that are passed down from generation to generation. They are responsible for eye color, hair color, blood type, and hundreds of other traits.

There are specific risks associated with genetic studies. To help you make your decision, additional information about participation in genetic studies is included at the end of this consent form. This information identifies how your personal information will be protected by the CALGB and its researchers.

Blood taken for these studies will be done only once at the time you enter the study. About 1 teaspoon full of blood would be taken.

2) I agree that my blood may be used for the genetic research studies described above.

Yes No Initials

Storage of your specimens:

The researchers would also like to store any portion of the tissue and blood that is not used up by the related studies described above. These samples may be stored indefinitely. You can still take part in the treatment study, and the research study described above without giving your consent for your samples to be stored.

It is not possible for you or the CALGB to know what studies of cancer may be appropriate in the future. We ask that you give permission in advance for other studies to be performed using the blood without being re-contacted to give permission for each test.

3) My specimens may be kept for future unknown use in research to learn about, prevent, treat, or cure cancer.

Yes No Participant Date

4) My specimens may be kept for research about other health problems (for example: causes of diabetes, Alzheimer's disease and heart disease).

Yes No Participant Date

5) My doctor or someone from CALGB may contact me in the future to ask me to take part in more research.

Yes No Participant Date

Where can I get more information?

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

1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

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

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

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

This study has been reviewed by the Missouri Baptist Medical Center Institutional Review Board (IRB). The Missouri Baptist Medical Center IRB is a Federally recognized, administrative group established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted at Missouri Baptist Medical Center. If you have any questions or concerns regarding this study, or if any problems arise, you may call the Principal Investigator at 314-996-5569. You may also ask questions or state concerns regarding your rights as a research subject to Dr. David Striker, Chairman of the Institutional Review Board, Telephone: (314) 996-5186.

Signature

I have been given a copy of all 14 pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study. I will also be given a signed copy of this consent form for my records.

Participant's Signature

Date

Investigator's Signature

Date

Missouri Baptist Medical Center



CALGB 90601-A Randomized Double-Blinded Phase III Study Comparing Gemcitabine, Cisplatin, and Bevacizumab (IND #7921, NSC #704865) to Gemcitabine, Cisplatin and Placebo in Patients with Advanced Transitional Cell Carcinoma

Authorization to Use and Disclose Personal Health Information for Study:

A federal government rule has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study.

This Authorization explains how your personal health information will be used and who it will be given to ("disclosed") for this research study. It also describes your privacy rights, including your right to see your personal health information.

By signing this Authorization form, you will give permission ("authorization") for the uses and disclosures of your personal health information that are described in this Authorization. If you do not want to allow these uses and disclosures, you should not participate in this study.

If you agree to participate in the research study, your personal health information will be used and disclosed in the following ways:

- The study doctor and staff (also known as the research team) will use your medical records and information created or collected during the study to conduct the study.
- The research team will send your study-related health information ("study data") to the sponsor of the study and its representatives ("sponsor"). If the sponsor conducts business related to clinical research in multiple countries around the world, this may involve sending your study data outside of the United States. Other countries may have privacy laws that do not provide the same protections as the laws in this country. However, the sponsor will respect the terms of this Authorization in all countries.
- The study data sent by the research team to the sponsor generally does not include your name, address, social security number, or other information that *directly* identifies you. Instead, the research team often assigns a code number to the study data, which may include your initials or other similar information. Some study data used or disclosed under this Authorization may contain other

information that could be used (perhaps in combination with other information) to identify you (eg, date of birth). If you have questions about the specific health information that will be used or disclosed pursuant to this Authorization, you should ask the study doctor.

- The research team and sponsor will use the study data for research purposes to support the scientific objectives described in the consent document and the process of getting regulatory approvals for its drugs, devices or other products.
- The sponsor or research team may add your study data to data from other studies in research databases so that it can study better measures of safety and effectiveness, study other therapies for patients, develop a better understanding of diseases, or improve the design of future clinical trials.
- Your study data, either alone or combined with data from other studies, may be shared with regulatory authorities in the United States and other countries, research teams at other institutions participating in the study, central study cooperative or monitoring groups, and the review board overseeing this study.
- Study data that does not directly identify you may be published in medical journals or shared with others as part of scientific discussions or training.
- Your original medical records, which may contain information that directly identifies you, may be reviewed by the sponsor, the ethical review board overseeing this study, and regulatory authorities in the United States and other countries. The purpose of these reviews is to assure the quality of the study conduct and the study data, or for other uses authorized by law. Portions of your medical record may be stored by the research team in the research record, as well.
- The sponsor may work with business partners in drug development. The sponsor may share your study data with these business partners, but only if the business partners need the information as a part of this work with the sponsor, and only if the business partners agree to protect your study data in the same way as the sponsor.
- Your medical records and study data may be held and processed on computers.
- Your personal health information or study data may be used or disclosed in any other manner or to any other person or organization referenced in the Informed Consent document to which this Authorization is attached or related.

Your personal health information may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team to these other parties.

You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor or research institution. However, to ensure the scientific integrity of the study, you agree that you will not be able to access or review such study information until after the study has been completed, when your access rights will be re-stored.

You may cancel your authorization at any time by providing written notice to the study doctor. If you cancel your authorization, you will no longer be able to participate in the study. However, if you decide to cancel your authorization and withdraw from the study, you will not be penalized or lose any benefits to which you are otherwise entitled.

If you cancel your authorization, the research team will no longer use or disclose your personal health information in connection with this study, unless the research team needs to use or disclose some of your personal health information to preserve the scientific integrity of the study or for other purposes for which the research team has relied upon your original authorization (e.g., to be paid for services). The sponsor, oversight boards and regulatory agencies may still use study data that was collected before you canceled your authorization for the original purpose(s) of those disclosures.

Your consent for the uses and disclosures described in this Authorization does not have an expiration date.

_____ Signature of Participant	_____ Date (by Participant)
_____ Participant Name (Print or Type)	_____ Participant Initials and Number (if applicable):

Complete ONLY if Authorization is signed by a legal representative of the Participant

_____ Signature of Legal Representative	_____ Date (by Legal Representative)
_____ Legal Representative Name (Print or Type)	
_____ If signed by Legal Representative, description of relationship to patient or other basis for legal authority	