

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A Randomized, Blinded, Placebo Controlled, Safety and Pharmacodynamic Study of BHT-3021 with Open Label Cross-Over in Subjects with Type I Diabetes Mellitus

PROTOCOL NO.: BHT-3021-01.08
WIRB[®] Protocol #20070637
IRB07132

SPONSOR: Bayhill Therapeutics, Inc.
San Mateo, California
United States

INVESTIGATOR: Carla J Greenbaum, M.D.
1201 9th Avenue
Seattle, Washington 98101
United States

SITE(S): Benaroya Research Institute
1201 9th Avenue
Seattle, Washington 98101
United States

**STUDY-RELATED
PHONE NUMBER(S):** Carla J. Greenbaum, M.D.
206-515-5232
206-223-6600
Hospital paging operator (24 hours)

**SUB-
INVESTIGATOR(S):** Srinath Sanda, M.D.
Jenna Bollyky, M.D.
Jane Buckner, M.D.

You are being asked to participate in this research study because you have type 1 diabetes mellitus. A research study is done when physicians, scientists and others want to try to find new ways of treating different illnesses. A research study is an experiment, and the effects of the experimental product that is being tested are not yet proven. Before you decide to be a part of a research study, you need to understand the risks and benefits (if any) of participating. This consent form provides information about the research study that is important for making an informed decision. It may include words or ideas that you do not understand. Please ask your study doctor or the study staff to explain anything that is not clear to you about this form or the study.

If you want, you may take an unsigned copy of this consent form home to think about it before making a decision. You also may talk over your decision with other people, such as family or friends, who can help you decide.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate the safety of an experimental (investigational) agent, BHT-3021, in subjects with type 1 diabetes mellitus (T1D). An investigational agent is one that is not approved by the U.S. Food and Drug Administration (FDA).

Patients with type 1 diabetes are thought to have an abnormal immune response. Usually the body's immune system attacks only foreign substances, but in people with type 1 diabetes the immune system attacks the person's own normal proteins, including insulin. This abnormal immunity causes inflammation in the pancreas, resulting in damage to the cells in the pancreas that produce insulin. BHT-3021 is an agent that is designed to decrease this abnormal immunity to insulin and to decrease damage to the insulin-producing cells in the pancreas. BHT-3021 contains pieces of a gene (DNA) that makes insulin. Investigators at Bayhill Therapeutics and your study doctors want to determine if BHT-3021 is safe and if it has an effect on the immune cells that may be responsible for causing damage to the insulin-producing cells in subjects with type 1 diabetes.

BHT-3021 has been tested in animals; however, this is the first clinical research study of BHT-3021 in humans.

HOW MANY SUBJECTS WILL TAKE PART IN THIS STUDY?

Up to 72 subjects will participate in this research study at approximately 10 centers globally. Each center will enroll up to nine subjects.

Up to four different doses (from 0.3mg to 6.0mg) of BHT-3021 may be tested to determine if there are any differences in safety or side effects. The dose you are given will be determined by how many people are in the study. You will not choose the dose of BHT-3021 that you receive.

Up to 18 subjects across the country will initially be enrolled into the study to receive the lowest dose of BHT-3021 or placebo. The placebo looks like the study drug, but has no medicine in it so that subjects in the study will not know whether they are receiving BHT-3021 or not. If a panel of independent doctors and other experts determine that the safety of the lowest dose in these subjects is acceptable, up to eighteen more subjects will be enrolled to receive a higher dose of BHT-3021 (or placebo). This process will continue until the highest level of BHT-3021 is tested. After completion of the dose-finding phase of the study, additional subjects may be enrolled to any one or more dose levels in order to obtain additional safety and efficacy data.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in this study, you will come in for a “screening visit”. During this visit you will have several medical tests to determine if you are eligible. During this visit, you will have:

- your medical history recorded;
- a physical examination;
- an examination of your eyes by an ophthalmologist;
- urine tests to detect possible effects of your diabetes on your kidneys;
- a urine pregnancy test (if you can get pregnant);
- and an electrocardiogram (ECG), which measures the electrical activity of your heart.

In addition, you will have blood drawn (60mL for routine blood work and 160mL for pancreatic function and immune system features, in total about 15 tablespoons) to check your overall health, your diabetes control; how much insulin your body is making; and some tests of your immune system.

If you are found to be eligible to participate in the study, you will be assigned randomly (like the flip of a coin) to one of two groups. For every three subjects who enter this study, two will be assigned to the group that receives BHT-3021 and one will be assigned to receive placebo at the start of the study.

The first group will receive BHT-3021, the experimental product that is being tested in this study. This group will receive BHT-3021 for 12 weekly injections followed by 9 months of study visits. Upon completion of the study visits, this group will continue to come in for additional visits for 12 months. The total time in the study will be just over 2 years.

The second group will receive placebo for the 12 weekly injections followed by 9 months of study visits. If it is determined that you received the placebo, you will then have an option to receive (BHT-3021) for 12 weekly injections followed by the same 9 month follow up. For this group, the total time in the study could be between 2 years to just over 3 years.

During the first 12 months of the study you will not know whether you are receiving (BHT-3021) or placebo. At the end of the first 12 months, you will be told which group you were in. However, this information is available to the study doctor at any time if needed in an emergency.

Study visit information:

You will receive BHT-3021 or placebo injections at weeks 0-11 (12 weekly injections). BHT-3021 or placebo is injected into the muscle in the upper part of one or both arms, depending on the dose you are receiving. You will be asked to remain in the clinic for one hour after each injection to detect any immediate reactions.

At each of these weekly injection visits, we will also be collecting blood samples and medical information. During some of the visits we will also perform a physical exam or other exams.

One month after the last injection you will need to come to the clinic for a study visit. At this visit we will collect blood samples, medical information and test how much insulin your body is making. This is called a Mixed Meal Tolerance Test. We will also do a physical exam at this visit. These tests will also occur at the next few visits, which occur every 3 months.

For those who received placebo for the first 12 months, you will then have the option of receiving the active BHT-3021 course. This will follow the same visit schedule as described above. After the second 12 months you will then enter the long term follow up period. During this period you will need to come in for study visits once every 6 months.

For those who received active BHT-3021 during the first 12 months, you will then enter into Long Term Follow Up. At this time you will need to come in for a study visit once every 6 months for one year. At each of these visits, we will collect blood samples, medical information and complete pancreatic function tests and physical exams. Other exams may also be done at this time.

Mixed Meal Tolerance Test (MMTT)

You will have an MMTT up to 13 times during the study to find out how much insulin your pancreas is still making. The MMTT will occur at the screening visit, week 5, week 15, and at months 6, 9, 12, 18, and 24. If you are originally in the placebo group you will have an additional 5 MMTT at week 5, week 15, and at months 6, 9 and 12. Before each MMTT, you will get special instructions about diet and insulin dosing. To make the blood sampling easier for the test, an intravenous needle and plastic tube (called an IV) will be placed in your vein. The IV will be kept in place during the test. Two blood samples taken ten minutes apart (one teaspoon of blood for each sample) will be drawn through the IV. You will then be given a drink called Boost, the “mixed meal”. This drink will raise your blood sugar and cause your body to produce insulin. After drinking Boost, one-half teaspoon of blood will be taken through the IV at regular intervals for up to four hours. The total amount of blood taken for the MMTT will not be greater than 3 tablespoons.

Intensive Diabetes Management:

If you decide to be in this study, you will receive what is called “intensive management” of your diabetes. The goal of this type of treatment is to keep your blood sugar as close to normal as possible. This will require you to take enough daily insulin injections to meet this goal. You could also be on an insulin pump instead of injections. During the study you will need to check your blood sugar levels frequently, and report them as often as once every two weeks to the study team. Your research study team will work with your personal diabetes health care team to keep your diabetes under good control.

Periodically, you will wear a device that is designed to continuously measure glucose levels through a sensor in the abdomen. This device is called a continuous glucose monitor and provides

minute-by-minute information about which way and how quickly blood sugar levels are changing. You and your doctor will be blinded to the results in the first year of the study. You may be allowed to keep this device which may help you to make adjustments that can result in better control of your blood sugar levels.

If the device gets appropriate regulatory approval for patient use, you may keep the device. Bayhill will not continue to provide sensors after the study is over so you will be responsible for obtaining sensors at your own cost or through your insurance company if they are covered under your plan.

HOW LONG WILL I BE IN THE STUDY?

The screening period may be up to six weeks (1.5 months). You will be in this study for approximately 25 months if you are assigned to the BHT-3021 group and up to 37 months if you are assigned to the placebo group.

Since BHT-3021 is a form of gene therapy, the FDA wants your study doctors to continue contact with you for two years after treatment with BHT-3021.

In the event of your death, an autopsy will be requested. This would be done to provide additional information about the research. Your family has the right to refuse the autopsy even if you sign this consent form.

WHAT ARE THE RISKS OF THE STUDY?

Study Drug Risks:

This is the first clinical research study of BHT-3021. BHT-3021 and procedures included in this study may involve unexpected risks that are impossible to predict. These unknown risks may affect you during your participation in the study and/or at some point in the future.

- Common side effects:

You may briefly experience fatigue (mild), fever, chills, malaise, headache, nausea, vomiting or diarrhea at the time of the injection. You may also develop mild tenderness, redness, swelling, itching or sensitivity at the site of injection.

- Glucose Control

Animal studies using BHT-3021 show that the study drug did not cause an increase in the immunological reaction to the cells in the pancreas that produce insulin. However, in humans, there is an unknown possibility that the study drug could increase an immunological reaction. This could result in further damage to your insulin producing cells. This damage may cause your body to need more insulin to control your diabetes or possibly may result in greater difficulty controlling your blood sugar. The study drug makes it more difficult for your body to use insulin.

- Markers of Autoimmunity

You may develop abnormal blood tests, including a rise in antibodies to the DNA. Antibodies to DNA have been found in people with other autoimmune diseases. If a rise in these antibodies to DNA was to occur, it is not known if this will be harmful. In a previous study using a product closely related to BHT-3021, these antibodies were not detected.

- **Other Possible Risks**

Another possible risk with use of this study drug is an increased level of cell mutation which could result in cancerous cell development. Since BHT-3021 has not been given before, we don't know if this will occur, but we think this risk is unlikely. There is the risk that any product containing DNA could cause permanent damage to your genes. The effects of such damage are not known. Even though BHT-3021 and other similar products have never been shown to damage genes in animals or humans, these results are not conclusive.

If you need to receive a vaccination (both live and killed), the vaccine should be administered in a different muscle group than that used for BHT-3021 or placebo. Please inform the study doctor of any vaccinations you receive during the study.

Receiving BHT-3021 may have other risks or discomforts that are not known at this time.

Reproductive risks:

This is the first clinical research study of BHT-3021. The risks of BHT-3021 on the fetus and your ability to have or to father children are not known.

Both women and men must agree to use birth control throughout the study. If you are sexually active, you must use a medically acceptable form of birth control (like hormonal contraceptives, intrauterine devices, condoms or surgical sterilization) while receiving BHT-3021 and for 3 months after the last dose of BHT-3021.

If you, or your partner, become pregnant, the study doctor will discuss the options available to you. If you suspect that you or your partner has become pregnant, you must notify the study doctor immediately. We will then ask to have information about your pregnancy and outcome.

Study Procedure Risks:

During the study you will undergo several routine diagnostic tests that have some risks.

- **Electrocardiograms:**

Electrocardiograms (ECG) involve placing electrodes on the skin over your chest, arms and legs to measure electrical impulses made by the heart. You could develop a rash at the site where the electrodes are placed.

- **Intravenous Needle and Blood Drawing:**

You may be at risk for side effects from having your blood drawn or having your IV placed. The risks of side effects from these procedures are small. There is sometimes soreness and/or a bruise at the site where the needle goes through the skin. Once in a while, people faint. It is rare, but some people may get an infection, a small blood clot, swelling of the vein and the area around it, or bleeding where the needle goes through the skin.

- **Mixed Meal Tolerance Test:**

Use of Boost during this test has no known side effects, but you may not like the taste.

Your condition may not get better or may become worse during this study.

Other Study Related Risks:

Research studies involving gene therapy have received a great deal of attention from the media. Although every effort will be made to protect your identity and that of your family, this attention may result in a greater risk than usual that information concerning your study participation will appear publicly without your consent.

WILL I BE NOTIFIED OF NEW FINDINGS?

If you decide to participate, your study doctor will keep you informed of any new findings that are discovered during the course of this study that might change your decision to be in this study. You may be asked to sign a revised consent form if this occurs. You may discontinue participation in the study at any time.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you decide to take part in the study, there is no guarantee that your health will improve. This study is not intended to provide you any direct medical benefit. It is intended to find out if BHT-3021 is safe. Your participation in this study may add to the medical knowledge about the treatment of diabetes.

COST TO SUBJECT

The study drug BHT-3021 will be provided at no cost by Bayhill Therapeutics, Inc. All of the tests and studies related to this research study will be paid for by the sponsor, while those required for your standard of care will be billed to your insurance company.

Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include the costs of treating possible side effects. Otherwise, you might have unexpected expenses from being in this study.

PAYMENT FOR TAKING PART IN THE STUDY

You will be paid \$100 for each completed study drug injection visit and \$100 for each completed study visit during the follow-up period that requires you to return to the clinic.

WHAT OTHER OPTIONS ARE THERE?

This is not a treatment study. Your option is to not participate.

COMMERCIAL DEVELOPMENT OF PRODUCTS

This study and any information gathered from your participation used in research may result in new products, tests or discoveries. In some instances, these may have potential commercial value. There are no plans for you to share in any financial benefits from these products, tests or discoveries.

WHAT ABOUT CONFIDENTIALITY?

Every attempt will be made to keep your participation in this research study and your records confidential, but we cannot guarantee absolute confidentiality. You will be assigned a unique identifying number that will be used in all study records. Only your study doctor and the research staff will have access to records that link your identity to the research records. However, representatives of the study sponsor, or designee, the U.S. Food and Drug Administration, other regulatory authorities and this medical center may inspect your clinic, hospital and research records to evaluate the results of this study. The results of this research study may also be published in scientific journals and/or may be presented at scientific meetings, but your identity will not be revealed.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits.
- Information gathered for this research about:
 - Physical exams
 - Laboratory and other test results
 - Study Diaries
- Records about any study product you received

Who may use and give out information about you?

The study doctor and the study staff.

Who might get this information?

- The sponsor of this research. “Sponsor” means any persons or companies that are:
 - working for or with the sponsor, or
 - owned by the sponsor.

Your information may be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries, and
- Benaroya Research Institute at Virginia Mason
- Virginia Mason Medical Center, and
- Western Institutional Review Board® (WIRB®)

Why will this information be used and/or given to others?

- to do the research,
- to study the results, and
- to make sure that the research was done right.

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

This permission will be good until December 31, 2050.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

WHAT WILL HAPPEN WITH MY BLOOD SAMPLES?

Some of the blood you give will be used to monitor your immune response. After these tests are done, any remaining samples will be stored for future research. This may include new tests of immunity, prognosis of type 1 diabetes, and quality assurance. The samples will not be used for genetic testing. The choice to keep left-over samples for future research use is up to you. If you want your samples destroyed after this study is complete, you should inform your study doctor. If you decide now that your samples can be kept for research, you can change your mind at any time. Just contact your study doctor and let him or her know that you do not want Bayhill to use your samples and they will be destroyed after this study is completed.

COMPENSATION FOR INJURY

If you get hurt or become ill while participating in this study and need immediate medical care, you should go to the nearest emergency room or urgent care center. Your study doctor who enrolled you in this study can take care of you or help you get the care you need. You will not be responsible for paying costs of that care if it is determined that your injury is a direct result of your participation in this study. Otherwise, the costs will be billed to you or your health care program just like your regular medical care costs. No other provisions have been made for compensation (including lost wages, lost time from work, or discomfort), and the costs of any other medical care will be billed to you or your insurance company. By signing this consent form you are not waiving any of your legal rights or releasing anyone from liability in case of negligence or other fault.

If you experience any side effects during the study, you should immediately contact Dr. Carla J. Greenbaum at 205-515-5232 or 206-223-6600 Hospital paging operator (24 hours) or one of the study team members at your site.

WHO IS FUNDING THIS STUDY?

Bayhill Therapeutics Inc., the sponsor, is funding this research. Your study doctor is being paid by the sponsor to conduct the study.

PARTICIPATION IS VOLUNTARY

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you discontinue study participation after receiving one or more doses of BHT-3021 / placebo, you will be asked by your study doctor to complete a final safety evaluation.

The study doctor or sponsor may stop your participation in this study at any time for any of the following reasons:

- new information suggests it may no longer be safe for you to continue;
- it is in your best interest;
- your condition has become worse;
- you become pregnant;
- you do not consent to changes made in the study plan;
- the sponsor ends the study earlier than planned;
- you are no longer able to perform the study procedures; and/or
- for any other reason.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions concerning your participation in this study or if you have questions, concerns or complaints about the research, contact:

Dr. Carla J. Greenbaum at 206-515-5232

If at any time you feel you have experienced a research-related injury or a reaction to the study agent, contact:

Dr. Carla J. Greenbaum at 206-223-6600 Hospital paging operator (24 hours).

If you have questions about your rights as a subject in a study, or if you have questions, concerns or complaints about the research, you may call:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will be given a copy of this signed and dated information and consent form and the Experimental Subject's Bill of Rights.

CONSENT

Site number: _____

Study Doctor: _____

Study No: _____

Subject I.D./Initials _____

I have read this consent form. My questions have been answered to my satisfaction.

I voluntarily consent to take part in this study.

By signing this consent form, I have not given up any of my legal rights.

I agree/do not agree (circle one and initial) to allow my blood to be stored and used for future research studies.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

I agree to my personal doctor being informed of my participation in the study.

Printed Name of Subject

Signature of Subject

Date

I certify that the subject signing this consent form has had the research fully and carefully explained and that the subject has been given an opportunity to ask any questions regarding the nature, risks, and benefits of his/her participation in this research.

Printed Name of Person Conducting
Informed Consent Discussion

Signature

Date

Signature of Investigator
(If different from above)

Date

EMERGENCY PHONE NUMBER

RESEARCH SITE

1 for subject

1 for researcher

1 to be kept with subject notes

| Study Schedule for those who Initially receive Active BHT-3021 | | | | | | | | | | | | | | | | | | | Long | Term |
|--|------|---|---|---|---|---|---|---|---|---|---|----|----|-----------------|----|-------|---|----|-------|------|
| | Week | | | | | | | | | | | | | | | Month | | | Month | |
| | -6 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 11+ 1 day | 15 | 6 | 9 | 12 | 18 | 24 |
| Physical exam | X | X | | X | | X | | X | | X | | | | | X | X | X | X | X | X |
| Eye Exam | X | | | | | | | | | | X | | | | | | | | X | X |
| Health questions | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| ECG | X | | | | | | | | | | | | | X | | X | | | | |
| Urine Test | X | X | X | X | | X | | X | | X | | X | | | X | X | X | X | X | X |
| Blood tests | X | X | X | X | | X | X | X | | X | | | X | X | X | X | X | X | X | X |
| Drug Injection | | X | X | X | X | X | X | X | X | X | X | X | X | | | | | | | |
| MMTT | X | | | | | | X | | | | | | | | X | X | X | X | X | X |

APPROVED
AS CORRECTED
May 08, 2009
WIRB®

| Study Schedule – Initially Receive Placebo (YEAR 1) | | | | | | | | | | | | | | | Treatment –BHT-3021 (Year 2) | | | | | | | | | | | | | | | | | | | |
|---|------|---|---|---|---|---|---|---|---|---|---|----|----|------------|------------------------------|---|---|------|---|---|---|---|---|---|---|---|---|---|----|----|------------|-------|---|---|
| | Week | | | | | | | | | | | | | | Month | | | Week | | | | | | | | | | | | | | Month | | |
| | -6 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 11 + 1 day | 15 | 6 | 9 | 12 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 11 + 1 day | 15 | 6 | 9 |
| Physical Exam | X | X | | X | | X | | X | | X | | | | | X | X | X | X | X | | X | | X | | X | | X | | | | | X | X | X |
| Eye Exam | X | | | | | | | | | | | | | | X | | X | | | | | | | | | | X | | | | | | X | |
| Questions | X | X | X | X | X | X | X | X | X | X | X | | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X | X |
| ECG | X | | | | | | | | | | | | | X | X | X | X | | | | | | | | | | | | X | | X | X | | |
| Urine Test | X | X | X | X | | X | | X | | X | | | | | X | X | X | X | X | X | X | | X | | X | | X | | | X | X | X | | |
| Blood Tests | X | X | X | | | X | X | X | | X | X | | X | X | | | | X | X | X | | X | X | X | | X | | X | X | X | | | | |
| Drug Injection | | X | X | X | X | X | X | X | X | X | | X | | | | | | X | X | X | X | X | X | X | X | X | X | X | | | | | | |
| MMTT | X | | | | | X | | | | | | | | | X | X | X | X | | | | | | X | | | | | | X | X | X | | |

**This is month 24 after being in the study. After completion of this visit, you will enter the long term follow up phase.

| Long Term Follow up (Year 3) | | |
|------------------------------|-------|------|
| | Month | |
| | 30 | 36/7 |
| Physical Exam | X | X |
| Eye Exam | X | X |
| Health Questions | X | X |
| ECG | | |
| Urine Tests | X | X |
| Blood Tests | X | X |
| Drug Injection | | |
| MMTT | X | X |

**VIRGINIA MASON INVESTIGATIONAL STUDY PARTICIPANTS
BILL OF RIGHTS**

The rights below are the rights of every person who is asked to be in a research study. As an investigational study participant, you have the following rights:

1. To be told what the study (research) is trying to find out;
2. To be told what will happen to you and whether any of the procedures, drugs or devices are different from what would be used in standard practice;
3. To be told about the frequency and/or important risks, side effects, or discomforts of the things that will happen to you for research purposes;
4. To be told if you can expect any benefit from participating and, if so, what the benefit might be;
5. To be told the other choices you have and how they may be better or worse than being in the study;
6. To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study;
7. To be told what sort of medical treatment is available if any complications arise;
8. To refuse to participate at all, or to change your mind about participation after the study has started. This decision will not affect your right to receive the care you would receive if you were not in the study;
9. To receive a copy of the signed and dated consent form; and
10. To be free of pressure when considering whether you wish to agree to participate in the study.
11. To be informed of any researcher's financial interest in the study.

If you have other questions, you should ask the researcher (your doctor). In addition, if you have questions about your rights as a research subject, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.