IRB Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
Feb 13, 2026

TITLE: A Pilot Clinical Study to Evidence Safety and Efficacy of Fracture Fixation of the Distal Radius using a Bioresorbable Bone Adhesive to Augment Metal Hardware

PROTOCOL NO.: DVAL24003-P
WCG IRB Protocol #20260262

SPONSOR: RevBio, Inc.

INVESTIGATOR: Name
Address
City, State Zip
Country

STUDY-RELATED PHONE NUMBER(S): Phone Number(s) [24 hour number required]

1. KEY INFORMATION:

A person who takes part in a research study is called a research or study subject. In this consent form "you" refers to the research subject.

You are being asked to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study.

Subject Initials _____
[OR]
Subject or Parent/Legal Guardian Initials _____
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[OR]
Subject/Legally Authorized Representative Initials _____

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 otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

The purpose of this study is to learn more about a device called Tetranite® Bone Adhesive for Extremity Fracture Fixation (TN-MFF), a biomaterial that will be used to augment the metal hardware fixation being used for your distal radius fracture. This adhesive is bioresorbable, which means it will disappear over time and allow your bone to grow in its place.

This study will enable the company to determine if the TN-MFF adhesive can provide immediate fixation of the fracture, and determine if the TN-MFF will fully resorb and encourage bone growth across the fracture. Successful completion of this study will enable the company to gather safety data to support further clinical studies in a larger population.

This is a Pilot study. A Pilot study is the first step of testing a new device in humans. It is a small-scale test of the methods and procedures to be used on a larger scale.

Tetranite Bone Adhesive for Extremity Fracture Fixation is an investigational device. An investigational device is one that has not been approved by the US Food and Drug Administration (FDA) as treatment for your condition.

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Procedures:

In this study, we will be collecting data from your medical record as you complete visits for your clinical care. We will also be asking you to complete some additional questionnaires about your quality of life.

If you decide to join this research study, it will take you about 1 year to complete the study. During this time, we will ask you to make **7** study visits to the hospital.

The following procedures are being performed for research purposes only:

- Copying information such as your medical history from your medical record;
- Healing assessment based on the location of the fracture;
- Study related imaging;
- Study questionnaires.

For a detailed explanation of the procedures, refer to the section of this consent form entitled, DETAILED PROCEDURES TO BE FOLLOWED.

Risks:

The possible risks associated with using TN-MFF are similar to risks that are associated with fracture fixation surgeries using traditional plates and screws or calcium phosphate cements when you are not participating in the study. The risks of TN-MFF have not yet been measured in people for this indication, but the material has been used in several experimental animals without serious adverse effects; these include studies to evaluate the biocompatibility and a one-year pivotal sheep study where the material was used as an augment to metal hardware in an aggressive intra-articular distal femur fracture. Some of the risks are those related to fracture

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fixation surgery in general and are the possibility of infection, inflammation, pain, loss of the material, hardware failure, and loss of reduction. There is the risk the fracture is not properly reduced or aligned during the procedure causing a step-off of the bone which may lead to irritation and compromised healing. In some cases, a revision surgery may be required to remove the metal hardware or TN-MFF and use an alternative form of fixation. There is also a risk of severe allergy to the material, but this material has been used in a human dental study for the past 12 months and no severe allergies have been observed in during that study. As part of the study, CT imaging will be required. However, due to the fact that bone is very distinguishable from soft tissue, a high resolution, low-dose CT image will be used

For a detailed list of the potential risks, refer to the section of this consent form entitled, RISKS ASSOCIATED WITH PARTICIPATION.

Benefits:

You will not receive any benefits from being in this study. The results of this study may help people with fracture fixation in the future because of what we will learn from this study.

Alternatives:

You cannot receive TN-MFF without participating in this study.

If you decide not to enter this study, there are other choices available. These include fracture fixation using the standard of care (metal hardware only). Ask the study doctor to discuss these alternatives with you. You do not need to be in this study to receive treatment for your condition.

You will receive medical treatment for your fracture whether or not you participate in the study.

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Voluntary Participation:
Your participation in this research 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.

Deciding to not take part in this research study will not change your regular medical care in any way.

What else should I know about this research?
There is a possibility that identifiers might be removed from your private information or biospecimens and then used or distributed for future research studies without your additional informed consent.

2. DETAILED PROCEDURES TO BE FOLLOWED:
Twenty (20) subjects will be participating in this study at up to four (4) centers, and approximately five (5) subjects will be participating at each site.

The study will take place at Cambridge Health Alliance. Additional sites may be added at a later date.

Cambridge Health Alliance
1493 Cambridge St
Cambridge, MA 02115

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Screening Visit - Visit 1 (this will take an additional 60-90 min. more than a typical standard of care visit)

After you sign this consent form, your study doctor will check your overall health, review your surgical plan and ask you questions to determine if you can participate in this study.

What will happen during the screening visit?

- Inclusion/Exclusion Determination: The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study.
- Demographic questions: You will be asked to provide personal information, such as your name, date of birth, gender, and ethnicity.
- Pregnancy testing: Your urine will be tested to see if you are pregnant. You will only have the pregnancy test if you are a woman and can have children.
    - The study staff will tell you if the pregnancy test results are positive.
    - The results of the pregnancy testing must be negative in order for you to be in the study.
- Review of Medical History: You will be asked to answer questions about your health, your medical history, and the medications you take.
- Physical Examination: A focused physical exam will be performed.
- Imaging – Radiograph: An X-ray will be taken on your injury site.
- Patient Reported Outcomes: The researchers want to know your thoughts and feelings about your pain level and the functional abilities of the injured extremity. This survey will include three questionnaires.

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Surgery Visit – Visit 2 (duration of this visit will be the same as the typical standard of care)
After you have been accepted into the study, your fracture fixation will be scheduled and performed using commercially available hardware, that will be augmented with the use of TN-MFF.

What will happen during the surgery visit?

- Ongoing Inclusion/Exclusion Determination: The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study.
- Surgery: The fracture will be repaired using commercially available hardware, that will be augmented by the use of TN-MFF. The use of the commercially available hardware will be as if you were receiving the same care regardless of the research.
- Imaging – Radiograph: An X-ray will be taken on your injury site.
- Imaging – CT: A routine clinical CT will be performed.
- Assessment of Adverse Events: The Investigator will determine if any adverse events occurred since the last study visit by speaking with you and reviewing any medical records.

Post-Operation Evaluation – Visit 3 (duration of this visit will be the same as the typical standard of care)
Two weeks after surgery, you will have your post-operative evaluation.

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What will happen during the Post Operation Evaluation (visit 3)?

- Physical Exam: A focused physical exam will be performed.
- Assessment of Adverse Events: The Investigator will determine if any adverse events occurred since the last study visit by speaking with you and reviewing any medical records.
- Imaging – Radiograph: An X-ray will be taken on your injury site.
- Patient Reported Outcomes: The researchers want to know your thoughts and feelings about your pain level and the functional abilities of the injured extremity. This survey will include three questionnaires.
- Functional Outcome: Range of Motion
- Clinical Assessment: A focused exam of your clinical healing.

Post-Operation Evaluation – Visits 4 (duration of this visit will be the same as the typical standard of care)

Visit 4 is a post-operative evaluation 6 weeks after surgery.

What will happen during the Post Operation Evaluation (visits 4)?

- Physical Exam: A focused physical exam will be performed.
- Assessment of Adverse Events: The Investigator will determine if any adverse events occurred since the last study visit by speaking with you and reviewing any medical records.
- Imaging – Radiograph: An X-ray will be taken on your injury site.
- Patient Reported Outcomes: The researchers want to know your thoughts and feelings about your pain level and the functional abilities of the injured extremity. This survey will include three questionnaires.

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- Functional Outcome: Range of Motion
- Functional Outcomes: Grip Strength
- Clinical Assessment: A focused exam of your clinical healing.

Post-Operation Evaluation – Visits 5 (this will take an additional 45-90 min. more than a typical standard of care visit)

Visit 5 is a post-operative evaluation 12 weeks after surgery.

What will happen during the Post Operation Evaluation (visits 5)?

- Physical Exam: A focused physical exam will be performed.
- Assessment of Adverse Events: The Investigator will determine if any adverse events occurred since the last study visit by speaking with you and reviewing any medical records.
- Imaging – Radiograph: An X-ray will be taken on your injury site.
- Imaging – CT: A routine clinical CT will be performed.
- Patient Reported Outcomes: The researchers want to know your thoughts and feelings about your pain level and the functional abilities of the injured extremity. This survey will include three questionnaires.
- Functional Outcome: Range of Motion
- Fracture Union: An assessment of your fracture healing.
- Functional Outcomes: Grip Strength
- Clinical Assessment: A focused exam of your clinical healing.

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Post-Operation Evaluation – Visit 6 (this will take an additional 45-90 min. more than a typical standard of care visit)
Visit 6 is a post-operative evaluation 26 weeks after surgery.

What will happen during the Post Operation Evaluation (visit 6)?

- Physical Exam: A focused physical exam will be performed.
- Assessment of Adverse Events: The Investigator will determine if any adverse events occurred since the last study visit by speaking with you and reviewing any medical records.
- Imaging – Radiograph: An X-ray will be taken on your injury site.
- Imaging – CT: A routine clinical CT will be performed.
- Imaging – HR-pqCT: A high resolution CT will be performed
- Patient Reported Outcomes: The researchers want to know your thoughts and feelings about your pain level and the functional abilities of the injured extremity. This survey will include three questionnaires.
- Functional Outcome: Range of Motion
- Functional Outcomes: Grip Strength
- Fracture Union: An assessment of your fracture healing
- Clinical Assessment: A focused exam of your clinical healing.

Post-Operation Evaluation – Visit 7 (this will take an additional 45-90 min. more than a typical standard of care visit)
Visit 7 is a post-operative evaluation 52 weeks after surgery.

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What will happen during the Post Operation Evaluation (visit 7)?
Physical Exam: A focused physical exam will be performed.

- Physical Exam: A focused physical exam will be performed.
- Assessment of Adverse Events: The Investigator will determine if any adverse events occurred since the last study visit by speaking with you and reviewing any medical records.
- Imaging – Radiograph: An X-ray will be taken on your injury site.
- Patient Reported Outcomes: The researchers want to know your thoughts and feelings about your pain level and the functional abilities of the injured extremity. This survey will include three questionnaires.
- Functional Outcome: Range of Motion
- Functional Outcomes: Grip Strength
- Fracture Union: An assessment of your fracture healing.
- Clinical Assessment: A focused exam of your clinical healing.

Your participation in this research study may be stopped by the study doctor *or the study sponsor* without your consent for any of the following reasons:

- Non-compliance with the protocol
- Failure to attend the follow-up visits
- Serious Adverse Event (SAE) or adverse event, which in the opinion of the Investigator prevents the subject's further participation in the study

If you decide to stop taking part in this research study, we ask that you tell your study doctor, and any information that you have already provided will be kept in a confidential manner. In addition, the study doctor will discuss further treatment options with you, and you will be asked

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to return to the clinic to have all the final clinical evaluations completed. You may ask that your identifiable samples be destroyed.

****ALL SITES:** The following risk information from [START] through [END] cannot be altered without submission of supporting documentation and/or Sponsor approval of changes. Submitted changes without appropriate documentation will be reverted during Board review.

[START]

3. RISKS ASSOCIATED WITH PARTICIPATION:

All devices can have side effects. Although not all or none of these side effects may occur, if they do occur, they may need medical attention. You must notify your study doctor about all symptoms, side effects, complaints, illnesses, or injuries which you experience during the course of the study regardless of whether or not you think these are related to the study device. You should discuss these with your study doctor as well as your regular health care provider, if you choose.

As a result of your participation in this study, you are at risk for the following side effects.

The possible risks associated with using TN-MFF are similar to the risks that are associated with fracture fixation surgeries using traditional plates and screws or calcium phosphate cements when you are not participating in the study: infection, inflammation, pain, loss of the material, hardware failure, and loss of reduction. There is the risk the fracture is not properly reduced or aligned during the procedure causing a step-off of the bone which may lead to irritation and compromised healing. In some cases, a revision surgery may be required to remove the metal hardware or TN-MFF and use an alternative form of fixation. There is also a risk of severe allergy

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to the material. This material has been used in a human dental study for the past 12 months and no severe allergies have been observed during that study.

There may be risks or side effects which are unknown at this time.

Other things to consider are the time commitment to complete the 7 study visits, over 1 year, at the hospital.

There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

The research may involve risks to you or to the embryo or fetus, if you are or may become pregnant, which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.
[END]

Radiograph Scan (X-Ray):
This study requires you to have radiograph (X-ray) of your fracture site. The X-ray scan involves low doses of radiation.

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This radiation exposure is necessary for some of your medical care but two (2) of the X-rays are for research purposes only.

The EPA calculates of radiation exposure for an X-ray of limbs and joints to be about 0.06 mSv or 6 mrem, and is approximately equivalent to a uniform whole-body exposure of 7 days of exposure to natural background radiation.

Computed Tomography (CT) Scan:
A part of this study requires you to have computed tomography (CT) of your fracture site. The CT scan involves low doses of radiation.

This research study involves exposure to radiation from a CT. This radiation exposure is not necessary for your medical care and is for research purposes only.

The total amount of radiation for a CT of the wrist is about 1.2 mSv or 120 mrem, and is approximately equivalent to a uniform whole-body exposure of 292 days of exposure to natural background radiation. This use involves minimal risk and is necessary to obtain the research information desired.

You may hear a slight buzzing, clicking, and/or whirring sound as the CT scanner moves around your body.

If you wear or have an electronic medical device, such as a pacemaker or a drug pump, please make sure you tell your study doctor and research staff. The Food and Drug Administration (FDA) has reported that CT scans may interfere with electronic medical devices such as pacemakers,

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defibrillators, neurostimulators, and implanted or externally worn drug infusion pumps. In the reports received by the FDA, CT scans may have caused unintended "shocks" from the neurostimulators, errors in insulin infusion pumps, and brief changes in pacemaker output pulse rate.

Pregnancy Risks for Females:
Females who are pregnant or nursing a child may not take part in this study. If you are a female and are able to become pregnant, you will have a urine test to make sure that you are not pregnant before you receive treatment in this study.

If you choose to take part in this study, you must use birth control such as:
sexual abstinence; birth control pills, birth control shots, IUD, birth control implants (placed under the skin by a health care provider), or patches (placed on the skin); sexual activity with a male partner who has had a vasectomy (surgery to become sterile); OR 2 forms of birth control, such as condom/diaphragm AND spermicidal foam or gel. You must also use this birth control for at least 365 days after your fracture fixation surgery.

If you think that you have become pregnant during the study, you must tell your study doctor immediately. Pregnant females will be taken out of the study.

Questionnaires/Surveys:
Completion of the patient reported outcome measures may make you feel uncomfortable or cause troublesome feelings or emotions. You may refuse to answer any of the questions and you may take a break at any time during the study.

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Photography:
Having your photograph taken may make you feel uncomfortable. You may take a break during any time of the study. There is also a potential risk of loss of confidentiality that someone who views your photograph might identify you.

4. CONFIDENTIALITY:

Research records/specimens

All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

All your electronic research records will be kept on an encrypted computer where your information is replaced with a code and password only known to the research personnel, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

Your de-identified research records will be transmitted to a third-party imaging review at Brigham & Women's hospital (Boston, MA) using an encrypted method (not regular email), where your information is replaced with a code and password only known to the entities below).

Your de-identified research records will be uploaded to an electronic data capture system and will be labeled with a code (will not contain any identifiable information about you).

A master key/list which links your name with the code on your research record will be maintained at the office of the primary investigator.

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Identifiers will be removed from your private information, and after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Medical Records
Information about your participation in this study or the results of procedures performed in this study will be placed in your medical record. As such, it may be available to your insurer. However, it will not be available to your employer, except with your explicit authorization and/or as permitted by law.

Presentations/Publications
While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

The results from this study may lead to new commercial products or tests. If this happens you will not receive any compensation.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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Limits to Confidentiality
Information obtained during the course of the study, which in the opinion of the investigator(s) suggests that you may be at significant risk of harm to yourself or others, may be reported to a third party to protect the rights and welfare of those at potential risk.

Authorization to Use and Disclose Protected Health Information for Research Purposes
Under federal privacy regulations, you have the right to decide who can review and copy your identifiable health information (called "protected health information" or PHI). PHI collected in this study may include information such as:

- Past and present medical records
- Records about your study visits
- Records about phone calls made as part of this research
- Research records

By signing this consent form, you are giving your permission for the study doctor and the study staff to get your PHI from your doctor and/or facilities where you have received health care. They may also share your PHI with:

- The Institutional Review Board (IRB) that reviews this research
- Researchers at Brigham and Women's Hospital
- Researchers at Dartmouth Medical Center
- Brigham & Women's Hospital (Image Central Review)
- The US Food and Drug Administration (FDA)
- Your medical insurance provider
- RevBio, which sponsors and provides funds for this research
- Prime Path MedTech, coordinates the study

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However, some of these organizations or institutions above do not have the same obligations to protect your PHI.

Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

Your PHI will be used for as long as the sponsor reports study information to the FDA. For sites in California, Delaware, Indiana, Illinois, and Washington, this permission will be good until December 31, 2070.

You may withdraw or take away your permission to use and disclose your PHI 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 the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study.

However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. Once the study is over, your right to review and copy your PHI will be reinstated.

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5. COMPENSATION AND TREATMENT FOR INJURY:

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide acute medical treatment, and will provide you with a subsequent referral to appropriate health care facilities.

If you are injured or get sick as a result of being in this study, you and/or your insurance will be billed for the costs associated with this medical treatment.

No compensation will be routinely available to you for any extra expenses that you may have as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.

No compensation will be routinely available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

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6. QUESTIONS:

Contact the study team at the phone number(s) listed in this document if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.

If you feel you have had a research-related injury, contact the primary investigator at the phone number(s) listed in this document.

You may contact WCG IRB, at855-818-2289, or clientcare@wcgclinical.com if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

7. PAYMENT FOR PARTICIPATION:

You will not be paid for participation in this research study.

Successful research using information about your health and your specimen (even if identifiers are removed) could result in commercial products, such as a device to secure extremity fractures. You will not share in any financial rewards associated with the development of these products.

8. COSTS OF PARTICIPATION:

There are no costs to you for participating in this study. Rev Bio will provide the study device free of charge during this study. You or your insurance company will be billed for all standard of care tests and procedures. Tests and procedures that are done only for research purposes will not be billed to you or your insurance company.

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9. FUTURE CONTACT:

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways:

- The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.
- Certified mail will be sent to you requesting that you call us.
- A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.

Put your initials on one of the lines below:

_____We CAN attempt to find/contact you in the above ways.

_____We MAY NOT attempt to find/contact you in the above ways.

Please note that if we lose contact with you and there is new information about your participation in the study that could affect your safety, we will attempt to find you or make contact with you in any way possible.

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10. CONSENT OF SUBJECT:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

Signature of Research Subject (21 years +)	**Date**	**Time**

Printed Name of Adult Research Subject

Signature of Person Obtaining Consent	**Date**	**Time**

Printed Name of Person Obtaining Consent

****For Sites in California****

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.

Who may use and give out information about you?
The study doctor and the study staff. They may also share the research information with an agent for the study doctor, if applicable.

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 <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA),
- Department of Health and Human Services (DHHS) agencies,
- Governmental agencies in other countries,
- The institution where the research is being done,
- Governmental agencies to whom certain diseases (reportable diseases) must be reported, and
- Institutional Review Board (IRB)

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, 2070.

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.

Authorization:
I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

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.

AUTHORIZATION SIGNATURE:

_____ _____

Signature of Participant **Date**