[Medical] Research Informed Consent

Title of Study: Clinical Trial of Etanercept (TNF-α Blocker) for Treatment of Blast-Induced Tinnitus

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The person providing medical oversight for this study at this site is Michael Carron, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, contact him by calling 313-577-0805.

Funding Source: Department of Defense (DoD)

Key Information about this Study

We are asking you to choose whether or not to volunteer for a research study being funded by the Department of Defense (DOD) to see if a medication called Etanercept (Enbrel®) compared to a placebo provides relief from tinnitus. The purpose of this initial description is to give you key information to help you decide whether or not to participate. We have included detailed information below. Ask the research team questions. Taking part in this study is completely voluntary. The purpose of this research study is to determine if Etanercept significantly reduces the severity of tinnitus (ringing in the ears) associated with history of blast and/or noise exposure or traumatic brain injury (TBI) and/or concussion. If you decide that you want to be in this study your participation will last for about 16 weeks (about 4 months).

What Are the Key Reasons You Might Choose to Volunteer for This Study?

It is possible that participating in this study may reduce your tinnitus and/or improve your hearing; however, it is also possible that you may not benefit directly from participation in the study. Information from this study may benefit other people with similar health issues in the future. For a complete description of benefits please refer to the Detailed Consent.

What Are Key Reasons You Might Choose Not to Volunteer for This Study?

You may experience adverse side effects related to the study medication. The most common side effects of Etanercept are injection site reactions such as redness, swelling, itching or pain and upper respiratory infections (sinus infections). Other side effects, such as increased risk of infection and cancer, can be serious and, in rare cases, have been fatal. For a complete description of risks, refer to the Detailed Consent. If you do not want to participate in this research study there are alternative treatments available for tinnitus. You should talk to the study doctor about possible alternative treatments for tinnitus before enrolling in this study. For a complete description of alternate treatment/procedures, refer to the Detailed Consent.

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Research Details

Purpose:
The purpose of this multi-site research study is to determine if Etanercept, compared to a placebo, significantly reduces the severity of tinnitus (ringing in the ears) associated with history of blast and/or noise exposure or associated with TBI and/or concussion. Individuals who qualify will be randomized into one of two groups: The group receiving the medication Etanercept or the group receiving a saline solution placebo.

Etanercept is a tumor necrosis factor (TNF) blocker that has been approved for use in adults for the treatment of Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, and Plaque Psoriasis. The FDA has not approved Etanercept for the treatment of tinnitus; therefore, the use of this medication for treatment of tinnitus in this study is considered investigational.

This study will enroll military personnel, veterans, and civilians who suffer from acute or chronic tinnitus associated with blast exposure and/or noise trauma or associated with TBI and/or concussion. The volunteer population(s) that will participate in the intervention will be recruited through military and Veteran's hospitals and other established otolaryngology and/or audiology clinics as well as through advertisements. The expected number of participants to be enrolled in this study at Wayne State University is approximately 60, with an additional 28 participants from other participating research sites across the United States for a total enrollment of 88 people at all sites.

How Long Will I Be in the Study?
If you decide that you want to be in this study your participation will last for about 16 weeks (about 4 months). Individuals who qualify to participate will come in for about 6 study visits. The study assessments required for the Baseline/Screening visit may take more than one day to complete. The study team will make every attempt to schedule all required procedures on the same day. Each visit will take anywhere from 1 to 3 hours of your time.

What Will Happen if I Take Part in the Study?
Everything done in this study will be done for research purposes. If you decide that you want to be in this study, once you have signed this consent form, you will need to undergo the following tests or procedures to determine if you qualify to participate. Although many of the procedures are routine to clinical practice, they are being done here for research purposes only and will not be completed if you decide not to take part in the study.

Screening/Baseline Procedures:
- Informed Consent: A research team member will explain the informed consent form and then ask you some questions to make sure you understand everything about the study. After you sign the informed consent form, you will be given a copy of it for your records. Your eligibility for the study will be determined during the first two weeks of your participation. If you are not qualified for the study during this initial period, you may be rescreened at a later date at the discretion of study staff.
- You will have a physical exam and your vital signs will be recorded including height, weight, blood pressure, heart rate, respiration (breathing) rate, and temperature.
- A blood sample will be collected for safety lab tests. The amount of blood needed for these tests is about 5 mL (1 teaspoon).

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- You will be asked questions about your current health, medical history and any medications that you have taken in the past or are currently taking. You may be asked to obtain a copy of your medical records from your primary care physician (PCP).
- If you are a woman of childbearing potential a pregnancy test will be done.
- You will be given a TB (Tuberculosis) test. About 6 mL of blood is needed for this testing (just over 1 teaspoon).
- You will be asked to complete questionnaires about your health, including mental health, and if you drink alcohol or have experimented with drugs, your hearing, and your tinnitus. The questionnaires will take approximately 45 minutes to 1 hour to complete. Should you qualify to participate in this study, some of these questionnaires may be repeated at follow-up visits.

Audiologic Testing

- You will have your ears examined and undergo a routine audiologic (hearing) test. An audiologist will look into your ears with an ear light to check for wax or other substances. In addition, he/she will check for obvious conditions that could interfere with the tests to be conducted. Second, foam ear-tips (similar to small insert stereo earphones) will be placed in your ear canals. You will be asked to listen and respond to tones of different pitches and at different loudness levels. Finally, you will be asked to repeat a series of words that you will hear at different loudness levels. During the audiologic assessment, the audiologist will insert a probe tip made of soft, pliable plastic into your ear canals and you will hear a soft tone and feel a slight change in air pressure. All of these procedures are similar to tests that normally are used to evaluate hearing in an audiology clinic. These tests are expected to take approximately 45 minutes to complete. Some of these tests may be repeated at follow-up visits.

Tinnitus Testing

- Using the same set-up as the hearing test, you will be asked to listen to a tone and compare the volume of the tone to the volume of your tinnitus. This test will be done to find the volume of an external tone that matches the volume of your tinnitus. You will also listen to a noise and be asked to respond when the noise covers up your tinnitus. These tests will take approximately 15 minutes and may be repeated at follow-up visits.

Study Treatment

If you qualify for the study after completing all of the screening procedures, you will then be randomly assigned (like the flip of a coin) to receive either Etanercept or a placebo (a substance that looks like the study medication, but which does not contain any actual medication in it) once a week for 12 consecutive weeks. Because this is a randomized trial, that means neither you nor the study staff can choose which group you will be in. That will be decided by chance. The study is also blinded which means that neither you nor the study team will know which treatment you are receiving. The medication will be given by a nurse or doctor as an injection under the skin (subcutaneous injection). You will have to come to the clinic once a week for 12 weeks in a row, to receive the study medication (or placebo).

Study Procedures

The following summary of study procedures will be done at some or all of the study visits:

- Your vital signs will be recorded including blood pressure, heart rate, respiration rate, and temperature (every study visit).
- If you are a woman of childbearing potential a pregnancy test will be done (Week 4).
- A blood sample will be collected for safety lab tests (Week 4 and Week 12). The amount of blood needed for these tests is about 5 mL (about 1 teaspoon).
- You will be asked questions about your current health, any illnesses or injuries you have experienced and medications you have taken or are currently taking (every visit).
- You may be given another TB (Tuberculosis) test (Week 12 or Week 16) if the study doctor feels it is necessary. About 6 mL of blood is needed for this testing (just over 1 teaspoon).
- You will be asked to complete questionnaires about your health and/or your hearing and tinnitus (Weeks 1, 4, 8, 12). Some of the questionnaires may be completed electronically/remotely via link sent by text or email.
- You will have audiologic (hearing) and tinnitus testing done (Weeks 4 and 12).
- You may not have all of the testing procedures done at every visit.

What is Expected if I Take Part in This Study?
If you decide to take part in this study, you will be required to do the following:

- Keep your study appointments and complete all study assessments. If you cannot attend an appointment, please contact study personnel (i.e., your study doctor or research staff) as soon as possible to schedule a new appointment
- Inform study personnel about any symptoms, changes in medications, doctor's or nurse's appointments, or hospital admissions that you may have had
- Agree to not participate in any other research study until you have completed this study
- Inform study personnel if you change your mind about participating in the study
- Inform your doctors that you are taking part in this study
- Inform the study if there has been a change to your contact information

What Possible Risks or Discomforts Might I Have if I Take Part in This Study?

The most common side effects of Etanercept include:

- Injection site reactions such as redness, swelling, itching, or pain. These symptoms usually go away within 3 to 5 days. If you have pain, redness, or swelling around the injection site that does not go away or gets worse, call the study doctor.
- Upper respiratory infections (sinus infections).

Other possible side effects seen with etanercept or medications similar to etanercept are as follows:

Risk of Infection:
Etanercept can lower the ability of your immune system to fight infections. Some people have serious infections while taking Etanercept. These infections include tuberculosis (TB), and infections caused by viruses, fungi, or bacteria that spread throughout their body. Some people have died from these infections. You will have a physical exam and the study doctor will review your medical history to make sure it is safe for you to start the study medication. In addition, you will have a TB test before

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starting the study medication and you may have another TB test at the end of the study if the study doctor feels it is necessary.

Risk of cancer:
There have been cases of unusual cancers, some resulting in death, in children and teenage patients who started using TNF-α blocking agents at less than 18 years of age. For children, teenagers, and adults taking TNF-α blocker medicines, including Etanercept, the chances of getting lymphoma or other cancers may increase. People with rheumatoid arthritis, especially those with very active disease, may be more likely to get lymphoma.

You should tell the study doctor if you have an infection or are being treated for an infection before starting the study medication. While you are taking the study medication you should tell the study doctor if you think you have an infection or have any symptoms of having an infection such as fever, sweats or chills, cough or flu-like symptoms, shortness of breath, blood in your mucus (i.e., coughing up bloody mucus), weight loss, muscle aches, warm, red or painful areas on your skin, sores on your body, diarrhea or stomach pain, burning when you urinate or urinating more often than normal, and feeling very tired. You should also tell the study doctor if you have any open cuts on your body or if you get a lot of infections or have infections that keep coming back.

Before starting the study medication you should tell the study doctor/research staff if you have recently received or are scheduled to receive a vaccine. People taking Etanercept should not receive live vaccines. Ask your doctor if you are not sure if you received or are scheduled to receive a live vaccine.

You should also tell the study doctor about any medicines you are taking before you start the study medication and you should be sure to inform the research staff about any new medications that you start while in the study. This includes any prescription and over-the-counter medicines, vitamins and herbal supplements you may be taking.

Previous Hepatitis B infection. If you have been previously infected with the hepatitis B virus (a virus that affects the liver), the virus can become active while you use Etanercept.

Nervous system problems. Rarely, people who use TNF-α blocker medicines have developed nervous system problems such as multiple sclerosis, seizures, or inflammation of the nerves of the eyes. Tell your healthcare provider right away if you get any of these symptoms: numbness or tingling in any part of your body, vision changes, weakness in your arms and legs, and dizziness.

Blood problems. Low blood counts have been seen with other TNF-α blocker medicines. Your body may not make enough of the blood cells that help fight infections or help stop bleeding. Symptoms include fever, bruising or bleeding very easily, or looking pale.

Heart failure including new heart failure or worsening of heart failure you already have. New or worse heart failure can happen in people who use TNF-α blocker medicines like Etanercept. If you have heart failure your condition should be watched closely while you take Etanercept. Call your healthcare provider right away if you get new or worsening symptoms of heart failure while taking Etanercept, such as shortness of breath or swelling of your lower legs or feet.

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Psoriasis. Some people using Etanercept developed new psoriasis or worsening of psoriasis they already had. Psoriasis is a skin condition that causes a skin rash with flaking, inflammation, and thick, white, silvery, or red patches of skin. Tell the study doctor if you develop red scaly patches or raised bumps that may be filled with pus. The study doctor may decide to stop your treatment with Etanercept.

Allergic reactions. Allergic reactions can happen to people who use TNF-α blocker medicines. The study medication will be given to you by a nurse or doctor in the clinic and you will be monitored for signs of an allergic reaction. If you develop signs of an allergic reaction you should seek emergency medical care. Signs and symptoms of a severe allergic reaction may include wheezing, having difficulty breathing or swallowing, fainting, or swelling of the face, eyelids, lips, tongue, or throat. Other possible signs of an allergic reaction include rash (hives, bumps, redness, or itchiness of the skin), chest pain, blurred vision, nausea, vomiting, or stomach pain. A severe allergic reaction requires immediate medical treatment and, if not promptly treated, could result in permanent disability or death. Regardless of severity, you should seek emergency medical care immediately if you experience any of the above.

Autoimmune reactions, including:

Lupus-like syndrome. Symptoms include a rash on your face and arms that gets worse in the sun. Tell your healthcare provider if you have this symptom. Symptoms may go away when you stop using Etanercept.

Autoimmune hepatitis. Liver problems can happen in people who use TNF-α blocker medicines, including Etanercept. These problems can lead to liver failure and death. Call your healthcare provider right away if you have any of these symptoms: you feel very tired, your skin or eyes look yellow, you have a poor appetite or are vomiting, you have pain on the right side of your stomach (abdomen).

Blood drawing.
There may be some discomfort, bruising, or bleeding at the site where the blood is drawn. Rarely, fainting occurs because of drawing blood.

Questionnaires.
Some people may become uncomfortable at being asked questions about mental health or substance (drug or alcohol) use. If, for any reason, you wish not to answer specific questions or you wish to terminate the session, you will be able to do so.

Audiologic/Tinnitus Testing.
Wax may need to be removed from your ears. If wax is removed from your ears, you may experience discomfort, skin irritation, minor bleeding, and/or abrasion of the ear canal that is temporary in nature. There is a remote risk of hearing damage if the testing equipment were to malfunction and emit a loud sound. Although this has never happened to our knowledge, it is a potential risk. Some people also find it uncomfortable to be in a sound booth to perform the testing. The testing may cause your tinnitus to seem louder than it was prior to testing.

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Reproductive Risks
The safe use of Etanercept in pregnant women and nursing mothers has not been established. Consequently, there may be risks to you (or to your embryo or fetus) if you are or may become pregnant that are unknown. Women of childbearing potential enrolling in this study must (i) have been using a birth control measure (an intrauterine device (IUD), birth control pills, a condom, diaphragm, or abstinence) for the previous three months, (ii) must have a negative pregnancy test, and (iii) must agree to continue to use a birth control measure for the duration of the study. If, while participating in the study, you suspect you have become pregnant, please contact the study physician immediately. Women are considered to be of childbearing potential unless they have been surgically sterilized (for example tubal ligation or hysterectomy) or are post-menopausal, that is, no menstrual period for more than 6 months. Nursing mothers may not participate in this study.

Loss of Privacy
Being in this study may result in a loss of privacy. Information that identifies you will be used in this study. A breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft or carry other risks affecting your ability to get insurance, current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history, status in the community, or could result in embarrassment. However, the research team will make every effort to protect your private health information and guard against any loss of privacy.

Risks of the usual care you may be receiving (medical care you are already receiving not related to this study) are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

What are the Possible Benefits of This Study?
You may or may not personally benefit from being in this study. It is possible that participating in this study may reduce your tinnitus and/or improve your hearing; however, it is also possible that you may not directly benefit from participation in the study. You may benefit by learning the results of your hearing test. The audiologist will explain the results of the evaluation and advise you if any additional evaluations seem necessary. You will also learn about your tinnitus. In some cases, people who are bothered by their tinnitus are helped simply by receiving information and having their questions answered. If you do not personally benefit from being in this study, by serving as a research participant, you may contribute new information that may benefit patients in the future.

What Other Choices Do I Have if I Do Not Want to Join This Study?
There are other forms of tinnitus therapy available. These methods include Cognitive-Behavioral Therapy, Progressive Tinnitus Management (an approach to tinnitus management that teaches patients how to manage their reactions to tinnitus using therapeutic sounds and coping techniques), and sound-based therapies (along with many others). No one method of treatment for tinnitus has been proven to be better than any other. Health care providers who might be able to help you include otolaryngologists (ear, nose and throat physicians), psychologists, psychiatrists, and audiologists. Your other choices may also include the following:

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- Getting rehabilitative care for your tinnitus and possible hearing loss without being in a study by seeing an audiologist to discuss if hearing aids would be appropriate for you
- Taking part in another study
- Getting no treatment

We recommend you talk to your doctor about your choices, including the risks and benefits of each choice, before you decide if you will take part in this study.

How Will My Private Information be Protected?
All information collected about you during the course of this study will be kept confidential to the extent permitted by law. You will be identified in the research records by a code name or number. Information that identifies you personally will not be released without your written permission. However, the study sponsor (Department of Defense), the Department of Defense Research Monitor, the Institutional Review Board (IRB) at Wayne State University, Wayne State University (Data and Monitoring Coordinating Center), Wayne State University staff/representatives (study monitoring), Sarah M. Theodoroff, PhD, CCC-A (Independent contractor providing audiology consultation services), or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), U.S. Army Human Research Protection Office (HRPO), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records. When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. A description of this clinical trial will be available on http://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.

Study Costs
The study sponsor will pay for all costs and charges from your participation in this research study. Participation in this study will be of no cost to you.

Compensation
To compensate you for your time and travel expenses you will be issued a debit MasterCard. You will use this same card for the entire study. You will receive $25 for completing all of the baseline/screening assessments and $25 for completing the study procedures for each study visit once you are enrolled in the study. Your payments will be loaded onto the debit MasterCard after each visit. There are approximately 6 study visits, therefore the total amount of money you will receive if you complete all of the baseline/screening assessments and all of the study visit assessments is $150. If you are asked to come in for additional visits to complete study assessments you may be compensated $25 for each additional visit. Additional compensation may be available for participants who live in the state of Michigan, but more than 50 miles from the research site (Detroit, Michigan).

Research Related Injuries
In the event that this research related activity results in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Wayne State University, the Detroit Medical Center or any other

facility involved with this study. If you think that you have suffered a research related injury, contact Michael Carron, MD at 313-577-0805 (After hours 313-745-0203, pager number 0978).

Do I Have to Take Part in the Study?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you decide to take part in the study you can later change your mind and withdraw from the study. You are free to only answer questions that you want to answer. You are free to withdraw from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other benefits and services you are entitled to receive. If you decide to withdraw from the study early the study doctor will ask that you come in for a final study visit. Any data collected up to the point when you stop participating in the study will be used for the study and any blood samples that have already been analyzed cannot be withdrawn from the study.

Right of Investigator to Terminate My Participation

The PI may stop your participation in this study without your consent. If you have any side effects that are very serious or if you become ill during the course of the research study you may have to drop out, even if you would like to continue. The PI will make the decision and let you know if it is not possible for you to continue. The decision that is made is to protect your health and safety, or because it is part of the research plan that people who develop certain conditions or do not follow the instructions from the study doctor may not continue to participate.

Questions

If you have any questions about this study now or in the future, you may contact Michael Carron, MD or one of his research team members at the following phone number 313-577-0805. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call the Wayne State Research Subject Advocate at (313) 577-1628 to discuss problems, obtain information, or offer input.

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Consent to Participate in a Research Study

To voluntarily agree to take part in this study, you must sign on the line below. If you choose to take part in this study you may withdraw at any time. You are not giving up any of your legal rights by signing this form. Your signature below indicates that you have read, or had read to you, this entire consent form, including the risks and benefits, and have had all of your questions answered. You will be given a copy of this consent form.

_____ Signature of participant / Legally authorized representative	_____ Date
_____ Printed name of participant	_____ Time
_____ Printed name of Legally authorized representative	
_____ Signature of witness**	_____ Date
_____ Printed of witness**	_____ Time
_____ Signature of person obtaining consent	_____ Date
_____ Printed name of person obtaining consent	_____ Time

**Use when participant has had this consent form read to them (i.e., illiterate, legally blind, translated into foreign language).

_____ Signature of translator	_____ Date
_____ Printed name of translator	_____ Time

Continue to HIPAA Authorization on next page

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HIPAA Authorization

A federal regulation, known as the "Health Insurance Portability and Accountability Act (HIPAA)" gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any protected health information collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The principal investigator (PI) and his research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and his research team in order to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

Your medical records, which may contain information that directly identifies you, may be reviewed by representatives from groups identified below. The purpose of these reviews is to assure the study is being conducted properly, that data is being obtained correctly or for other uses authorized by law. These reviews occur at the study site or in the PI's research office and can take place anytime during the study or after the study has ended.

The PHI that will be "USED" for this research includes the following: name, address (street address, city, state and zip code), e-mail address, elements of dates, telephone numbers, social security number, medical record number, and any unique identifying numbers or characteristics or code.

The PHI that will be "DISCLOSED" or shared with others for this research includes the following: elements of dates and any unique identifying numbers or characteristics or code.

Your study information may be **used** or **shared** with the following people or groups:

- The PI, co-investigators, and key personnel of Wayne State University (WSU) and Wayne Health associated with the research project
- WSU's Institutional Review Boards (IRB)
- Authorized members of WSU's and/or Wayne Health's workforce who may need to access your information in the performance of their duties. [*For example, to provide treatment and services, ensure integrity of the research, or for accounting and/or billing matters.*]
- Other collaborating institutions or individuals, which include: Quest Diagnostics (Laboratory processing TB tests); Sarah M. Theodoroff, PhD, CCC-A (Independent contractor providing audiology consultation services).
- The study Sponsor or representative, including companies it hires to provide study related services, which include: The Department of Defense (study sponsor).
- Federal agencies with appropriate regulatory oversight (e.g., FDA, OHRP, OCR, etc.) may review your records.

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Once your information has been released according to this Authorization, it could be released again and may no longer be protected by the HIPAA regulations.

This Authorization does not expire. The research team may need to correct it or provide missing information about you even after the study has ended, and your medical records may be needed to assist in this process.

- During your participation in this research project you will not be able to access that part of your medical record involved in the research. This will be done to prevent the knowledge of the research results from affecting the reliability of the project. Your information will be available to the treating physician should an emergency arise that would require for him/her to know this information to best treat you. You will have access to your medical record when the study is ended or earlier, if possible. The PI is not required to release research information that is not part of your medical record.

You may withdraw (take back) your permission for the **use** and **disclosure** of your PHI for this research at any time, by **writing** to the PI at the address on the first page of this form. Even if you withdraw your permission, the PI for the research project may still use your PHI that was collected prior to your written request if that information is necessary to the study. If you withdraw your permission for use of your PHI, you will also be withdrawn from the research project. Withdrawing your authorization **will not** affect the health care that will be provided by the Detroit Medical Center and/or the WSU School of Medicine Practice Plans.

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Authorization to use and disclose PHI

- By signing this document, you are authorizing the PI to **use** and **disclose** PHI collected about you for the research purposes as described above.

Signature of participant	Date
Printed name of participant	

- For participants unable to give Authorization, the following individual is acting on behalf of the research participant (e.g., children, mentally impaired, etc.).

Signature of authorized representative	Date
Printed name of authorized representative	Relationship to the participant
Signature of person obtaining Authorization	Date
Printed name of person obtaining Authorization	Time

Participant's Initials