# Combined Consent to Participate in Research and HIPAA Research Authorization

**TITLE:** Electroencephalogram (EEG) combined transcranial magnetic stimulation (eTMS) for chronic trauma and stressor-related disorders (TSRD) (eTMS for Stress)

**PROTOCOL NO.:** BEP-001-G220325
WCG IRB Protocol #20230584

**SPONSOR:** BEP Medical Group, LLC

**INVESTIGATOR:** Marcia A. Bockbrader, MD, PhD
2929 Kenny Rd
Ste 100
Columbus, Ohio 43221
United States

**STUDY-RELATED PHONE NUMBER(S):** 614-670-4000
614-344-6127 (24 hours)

Taking part in this research 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 any 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.

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully, discuss it with friends and family, and ask any questions you have before making your decision to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with BEP Medical Group, LLC. If you are a BEP Medical Group patient or employee, your decision will not affect your care or employment status.

- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or serious.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and you will receive a copy of the form.

**Key Information About This Study** The following summarizes study information to help you decide whether or not participate (more details are given later in this form):

The purpose of the research is to **better understand the role that EEG-guided transcranial magnetic brain stimulation (eTMS) can play as part of a treatment program to address chronic trauma and stress-related disorders, mental health and/or substance use problems common among Veterans**. Standard testing and treatments (see Table 1) that will be given with eTMS include medical and psychosocial testing, blood tests, medication monitoring and adjustment, counseling, education, integrative therapies, lifestyle coaching using fitness trackers and a wellness app, and Veteran support services. Research procedures in this study include: (1) at least 30 sessions of in-clinic eTMS, which is being provided under a US Food and Drug Administration (FDA)-approved investigational device exemption (IDE) to collect information about its safety and treatment effects, (2) brain activity testing through electroencephalograms (EEG), and (3) optional sleep studies (also called polysomnograms, PSG). Clinical data captured through (4) cognitive testing, (5) biometric testing, and (6) questionnaires of symptoms and quality of life will also be used for research purposes. Study duration is 6-9 months, including initial screening, baseline testing, 8 weeks of daily treatments, and a follow-up stage with home Telehealth monitoring, and periodic in-person visits. The most common risks of eTMS are potential for headache and changes in sleep or mood; the most serious risks of TMS are potential for seizures, though this risk occurs rarely. Study investigators will monitor you closely to minimize these risks. Appropriate alternative courses of treatment include private, county or VA treatment programs.

Table 1. Clinical care (standard treatments) & experimental (research) procedures

| | **Standard treatments** | **Research procedures** |
|---|---|---|
| Part I:<br><br>Baseline and initial evaluation | Treatment consent<br>Medical history & medication monitoring<br>Physical & neurologic exam<br>Hearing screening<br>TMS screening | Research Consent<br><br><br>Repeat hearing screening<br>Randomization<br>Sleep study |

| | | |
|---|---|---|
| Months 0-3 | Vital Signs (blood pressure, heart rate, balance, oxygen saturation, EEG, grip strength, heart rate variability)<br>Labs (blood work, drug screen) | |
| | Psychosocial cognitive evaluation<br>Military service history<br>TBI history | Repeat cognitive screening |
| | Clinical screening questionnaires and patient reported outcomes (PRO) about wellness, mood, pain, stress, sleep/fatigue, quality of life, substance | Questionnaires about treatment expectations, handedness |
| | Physician, pharmacist, and nurse visits Complementary and alternative medicine<br>Counseling and cognitive-behavioral therapy<br>Veteran peer mentoring<br>Wellness education<br>Smartphone wellness app<br>Wearable fitness tracker biometrics | Safety monitoring<br>Determine eTMS motor threshold<br>30 sessions of eTMS (in clinic)<br>Side effects questionnaire |
| Part II: Follow-up Months 4- | Quarterly re-evaluations<br>Clinical screening questionnaires and PRO (above)<br>Neurovitals (above)<br>Smartphone wellness app<br>Wearable fitness tracker biometrics<br>Telemedicine visits<br>Veteran peer mentoring | Sleep study |

**INFORMATION REQUIRED BY THE FDA:** eTMS is being used under an FDA-approved investigational device exemption (IDE) to evaluate a new indication of an approved device. The FDA considers this treatment experimental and significant risk. Prior to enrolling, you will complete an eTMS screening questionnaire to evaluate whether you have any of the following conditions, as they can be unsafe with eTMS:

- Metal in the head, except mouth (e.g., cochlear implant, implanted brain stimulators, aneurysm clips)
- Increased intracranial pressure (which lowers seizure threshold)

Individuals must be 22 years of age or older to participate. If you have any of the following conditions, you should discuss the risks versus benefits of participation with the study medical director and your primary care physician:

- Medical implants, including cardiac pacemakers, intracardiac lines, implanted neurostimulators or medication pumps

- Heart disease that causes moderate to severe symptoms and/or is characterized by moderate to severe pathology, including: (a) a recent history (past 3 months) of heart attack (myocardial infarction), (b) heart failure with an ejection fraction of less than 30%, or (c) heart failure with a New York Heart Association Functional Classification of Class III or IV
- Bipolar disorder diagnosis
- History of stroke (especially in past 3 months) or other brain lesions
- Pregnancy
- History of suicide attempt(s)
- Personal or family history of epilepsy
- Medications that lower seizure threshold
- Heavy alcohol consumption within 48 hours prior to TMS.

If you have had a heart attack or stroke in the past 3 months, we may need clearance for your participation from your cardiologist or neurologist.

**IMPORTANT: Participants are asked to limit alcohol intake to two (2) drinks per day during protocol participation to minimize risk for seizures.**

**Detailed Study Information**

## 1. Why is this study being done?

You are being asked to take part in this clinical trial because you are a Veteran with exposure to chronic stress and/or trauma who is seeking treatment. The purpose of this study is to allow the investigation of a new indication for eTMS when combined with usual therapies, to see if it is safe and helpful to Veterans suffering from chronic stress and trauma-related conditions associated with their military service. Some study participants may also have a history of traumatic brain injury (TBI), mood changes, chronic pain, difficulty sleeping, and opioid or alcohol use.

eTMS is a brain stimulation method that sends a magnetic pulse through the surface of the skull to certain areas of the brain. Changes in magnetic fields in the brain shift electrical currents, which may affect brain activity and function. eTMS, as it is being used in this study, is an experimental procedure. This means its use is considered off-label, or investigational.

During the study, we will gather information about whether eTMS is safe for Veterans with chronic stress-related problems. We will also learn whether eTMS that is given as part of a comprehensive wellness program changes sleep patterns, mood symptoms, substance craving, and other neurologic responses. The IRB has approved the conduct of this experimental study.

## 2. How many people will take part in this study?

Up to 30 Veterans with symptoms of chronic stress and trauma exposure will enroll.

## 3. What will happen if I take part in this study?

If you participate in this study, you will have to go through the clinical treatments and research procedures described below and in Table 1.

We are asking your permission to **take videos or pictures** of you during sessions described in this consent. Videos will include the position of the EEG or eTMS magnet on your head during treatment. These videos will be used to verify treatment locations that are used across patients. We will not share identifiable pictures of your face with people outside the study without your consent. If we use your videos for educational purposes, your videos will be changed so that no one will be able to know who you are.

Do you agree to be videotaped during the study? Yes:___ No: ___

**Part I: Screening, Evaluation, Intensive Therapy and eTMS**

- **Baseline Assessments** (approximately 1-2 weeks). We will:
  - Review your **medical and psychosocial history**, including any history of traumatic brain injury, mental health issues or substance use, and your **medications.**
  - Perform a **physical and neurological exam.**
  - Check **screening blood tests** for hormone levels and body metabolism.
  - Perform brief **cognitive tests.**
  - Gather information on **questionnaires** about your mood, sleep, pain, stress, coping, substance craving, quality of life, lifestyle habits, military service history, and psychosocial needs.
  - Assigned you a **Veteran peer mentor** to help you throughout the program.
  - Perform **neurological** testing. These studies are routinely performed in the clinic by BEP Medical Group, LLC staff. Only approved, trained, and highly experienced technicians involved in the study will perform these assessments, which will include:
    - **EEG.** You will participate in recording of your brainwaves while you are resting or performing tasks.
    - **PSG (Sleep study)**. You may participate in a study to evaluate your sleep rhythms, duration of sleep, and quality of sleep.
    - **Audiometry (Hearing test).** You will participate in a test of your hearing while you wear headphones and listen for words or tones.
  - Perform **therapist and athletic trainer evaluations** of your level of physical fitness.

- Provide you with a **wearable fitness tracker**, which will help you track fitness and wellness goals. This monitor will report your sleep, activity, pulse and other measurements to your phone to give you personalized feedback in a fitness app.
- Enroll you in **Athena Patient Portal**, so that you can contact your medical and study team and complete Telehealth visits.
- Enroll you in the **study Fitness Tracking** app, so that your wearable sensor data can be collected for the study. Data is kept protected in a HIPAA-compliant database. Your data will be used to track your response to study treatments and give you personalized performance feedback.
- Show you how to use the fitness tracking app and education websites on your smartphone. If you do not have a smartphone, we will provide one for you to use during your time in the study.

- **Intensive eTMS Clinic Visits** (approximately 6-8 weeks)**.** You will participate in education, counseling, complementary and alternative medicine treatments, physician visits, therapy, nurse visits, medication adjustments (as needed), and eTMS sessions:
  - You will see a **physician or nurse practitioner** who specializes in eTMS at least weekly. You may also see experts in brain injury, pain and/or addiction medicine. Appointments may be in person or by Telehealth visits. During these visits, we will review how you are feeling, what medications you are taking, how you are sleeping, and address any of your concerns.
  - **EEG-guided Transcranial Magnetic Stimulation (eTMS).** You will come to the clinic five (5) days per week for six (6) weeks for **30 TMS sessions**. At the beginning of each session, we will determine your motor threshold (MT), which is the minimum magnetic pulse strength needed to cause a muscle twitch. We find this threshold by holding the magnet against your scalp just above your ear and adjusting the pulse strength until we find the setting that sends a signal from your brain to your hand, causing a small visible muscle twitch. The purpose of this procedure is to adjust the stimulation intensity so that it is as small as possible and produces approximately the same effect on each participant on each day that they get eTMS.
  - **Pre/Post Treatment Neurovitals Monitoring**. Before and after eTMS, we will check your pulse, blood pressure, oxygen saturation, temperature, grip strength, balance, and brain rhythms (2 min EEG, except for the first baseline EEG which is 10 minutes).
  - **Comprehensive Wellness Program** (approximately 8 weeks). Your treatment will be personalized to you and may include:
    - **Cognitive Behavioral Therapy** with counselors and psychologists for coping, stress, and mental health management (weekly).
    - **Medication Management** with a clinician (weekly).

- **Fitness, Nutrition and Wellness Education** with certified wellness professionals (massage therapists, dieticians, and/or personal trainers) to assess your body mechanics, address muscle and joint pain, review your diet, and create a personalized wellness program (weekly).
- **Complementary and Alternative Medicine Visits** for aromatherapy, guided meditation, acupuncture, chiropractic, or cranial-sacral therapy.
- **Data-driven human performance** biometrics to track your resilience and fitness goals (daily), used by elite athletes to optimize fitness.
- **Veterans peer mentor support** (available 24/7).

- **Repeat Assessments** (weeks 3 and after week 6)**.** You will repeat baseline evaluations after completing the first two (2) weeks of TMS and then after the six (6) week intensive program.

**Part II: Follow-Up Visits** (months 2-9). We will continue to monitor you remotely through health trackers and scheduled clinical visits for approximately 6-9 months. During this time, you will have access to the **eTMS** education and support teams **and** remain in contact with your **Veteran peer mentor(s)**.

- You will be asked to answer questions by web every few weeks.
- You will return to clinic or complete Telehealth visits for follow-up (12, 24, 36 weeks). At these visits, you will repeat baseline evaluations and we will update your medical and mental health information.
- At follow-up visits, you will be asked about your **satisfaction** with the program and opinions about participation so that this can be reported to the sponsor.
- You will be connected with **Veterans resources in your community** to help you maintain healthy habits, access to good quality health care, and achieve life, education or work goals you have identified.
- Once you complete the final study visit, you will be referred to options for continuing medical care if you need it.

## 4. How long will I be in the study?

You are expected to be in the study for about six (6) to nine (9) months including the screening period, but weekly time commitments will vary during the study. We have flexible scheduling times to fit your needs, and many of the follow-up activities can be done through your phone or computer. Sessions will include:

- Baseline testing phase (1-2 weeks): You will participate in three (3) to six (6) sessions over two (2) weeks. Each session will last up to three (3) hours, except for the sleep study, which requires an overnight visit in the sleep lab. Total time will be up to nine (9) hours weekly, plus the sleep study (6-8 hours).
- Intensive treatment phase (6-8 weeks): You will participate in five (5) sessions a week for a six (6)-week block which may occur at the beginning, middle or end of the 8-week period. You will have 1-3 visits per week in the other two (2) weeks. Each session will last up to two (2) to three (3) hours, except for the

sleep study (6-8 hours, overnight). Daily sessions may include eTMS and another clinic visit. Total time will be up to twelve (12) hours weekly.
- Depending on your response, you may be eligible to repeat treatment phases.
- Follow-up phase (approximately 30 weeks): In the follow-up portion of the study, you will return to clinic quarterly for comprehensive follow-up visits (weeks 12, 24 and 36). Each follow-up session will last up to 4 hours, except for the optional sleep study which requires an overnight visit in the sleep lab.
- Throughout the course of the study, you will be asked to interact with the fitness app for a few minutes per day and answer questions by web every few weeks (lasting 30 minutes or less).
- At study completion, you may choose to enroll in a separate long-term neuromodulation and fitness tracking study to continue eTMS.

## 5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with BEP Medical Group. If you decide to leave the study, appropriate steps will be taken to ensure you have adequate follow-up (e.g., referrals to other medical and mental health providers). You will be asked to return any wearable health monitors or other study resources you used during participation.

The investigators of the study may also terminate your participation in the study with or without your consent for any medical reasons, mental health concerns, or if you do not complete scheduled study procedures or follow-up visits.

## 6. What risks, side effects or discomforts can I expect from being in the study or participating in the clinical program?

The procedures for this study may involve risks that are not known or expected. The following are known risks:

**EEG-guided Transcranial Magnetic Stimulation (eTMS) Risks**

The FDA has determined that eTMS is a significant risk procedure in this protocol. eTMS is a form of non-invasive brain stimulation that uses a magnet to create electrical fields around neurons in the brain. The long-term effects of eTMS are unknown. Side effects of eTMS are usually mild and temporary; most stop as soon as the eTMS is stopped. You may need to avoid driving immediately after eTMS due to *commonly reported eTMS side effects, including:*
- Headaches, scalp discomfort, or tooth/jaw pain that can be mild or severe
- Tingling, numbness, spasms or twitching of facial muscles
- Lightheadedness, hearing or vision changes
- Discomfort from stimulation noise

*Rare but serious side effects include*:

- Seizure or syncope (temporary loss of consciousness)
- Changes in sleep, mood, or behavior, including mania
- Permanent hearing loss, especially if earplugs fall out

You will be closely monitored (by video or in-person) for any of these serious adverse effects, including signs of seizures or muscle twitching. If serious side effects occur, testing will stop immediately, medical care will be provided, and you must remain in clinic until cleared medically. The eTMS portion of the program may be discontinued (with or without your consent) if side effects persist.

**If your mood symptoms worsen or you have suicidal thoughts**, tell your study team, Veteran peer mentor, primary care physician, and/or friends or family immediately so that we can connect you with help. If you need help immediately or feel you cannot tell friends, family or study staff about how you are feeling, please contact any of these resources, available 24/7:

- VA Veterans Suicide Crisis Line: 1-800-273-8255 (press 1) or text to 838255
- National Suicide Prevention Lifeline: 1-800-273-8255 or 988 (by 1/16/22)
- Homeless Veterans Crisis Line: 1-877-424-3838
- OhioMHAS Substance Crisis Line: TakeChargeOhio.org, 1-877-275-6364

You may also call 911 or go to your nearest emergency department (ED).

To minimize eTMS-related side effects:

- Remove all forms of eye makeup, especially eyeliner, eye shadow and mascara, that may contain ferromagnetic pigments before eTMS sessions.
- Low stimulation intensity will be used to minimize seizure and headache risk. If you have headaches, tell study personnel who will adjust the eTMS.
- You will be offered earplugs to protect your hearing during stimulation. To minimize risk of hearing loss, you should wear these earplugs during eTMS and immediately report if they become loose or fall out. We will stop the stimulation if you report/we observe that this has happened. In the event your hearing changes with eTMS, you will be referred to a specialist.
- If you notice visual changes, tooth pain, or facial twitching during eTMS, please tell study personnel. These symptoms can be caused by facial/scalp nerve stimulation and may stop if stimulation is adjusted.
- Acetaminophen or other medications for treatment of minor pain and headache will be available in the clinic to minimize discomfort.
- If you feel lightheaded, faint, or like you are going to pass out, please tell study personnel who will stop stimulation. Please get up slowly if you feel lightheaded.
- You will be offered snacks after eTMS. It is important to eat or drink after eTMS to reduce the likelihood of low blood sugar and headaches.

- Pre-/post-eTMS EEGs will be conducted (for 2 minutes each) to find each person's best stimulation frequency and monitor for seizure-related brain responses.
- Medical personnel trained in seizure management, basic life support (e.g., CPR), and appropriate life-support equipment will be available during eTMS. In the event of seizures or syncope, EMS will be called to take you to the ED where anti-seizure medications will be available.
- Individuals who experience seizures or convulsive syncope with eTMS may have difficulty with future employability, insurability, or eligibility to drive. If this occurs during the study, we will provide you with a letter stating that the event was experimentally produced to minimize risk of loss or denial of employability, motor vehicle licensure and insurability.

**Electroencephalography (EEG) Risks**
During an EEG, you will either be asked to sit quietly with your eyes closed or to perform an action. You will wear a wireless headset with dry EEG electrodes that will touch your scalp and record your brain waves. (No gel or paste is needed with this type of headset.) No brain stimulation or radiation is given with this type of recording. There are no health risks associated with EEG, although some people report discomfort with testing, including scalp discomfort or headache.

**Polysomnography (PSG) Risks**
During a PSG, you will come into the sleep lab overnight (about 8 hours) where we will record your limb movements, heartbeat, breathing, eye movements, blood oxygen levels, and brain rhythms while you sleep. You will wear sensors on your scalp, temples, chest and legs. No brain stimulation or radiation is given with this type of recording. PSG is painless and noninvasive. Potential side effects or discomforts that could occur due to the PSG study include difficulty sleeping and skin or scalp discomfort at the site of recording electrodes. <u>You should avoid consuming alcohol or caffeine during the afternoon and evening of the test as both of these can affect sleep patterns and make it more difficult to sleep</u>.

**Blood draws (routine clinical labs)**
You may experience discomfort associated with drawing blood for hormone tests and routine labs. Experienced technicians will be used to minimize discomfort.

## 7. What benefits can I expect from being in the study?

Participation in the Ohio eTMS Trial is expected to provide social support through Veterans programs, and to help you develop and maintain lifestyle habits and coping strategies to maximize well-being and overall function. There are remarkable benefits of exercise, both physical and mental, and a new fitness routine can be a helpful part of any treatment plan for chronic stress-related conditions. While eTMS has helped some people with depression or headaches

feel better, we do not know if there will be benefits to you from eTMS. Your participation in this study may give us more information to develop better treatment strategies for Veterans in the future.

## 8. What other choices do I have if I do not take part in the study?

You may choose not to participate. There will be no penalty to you or loss of benefits to which you are otherwise entitled. An appropriate alternative would be to contact county or Veteran Administration behavioral health resources.

**This trial is not intended to provide crisis intervention.** If you think you have a medical or mental health emergency, call 911 or go to the nearest ED.

**If you need to talk with someone right away, contact the Veterans Crisis Line.** Whatever you're struggling with—chronic pain, anxiety, depression, trouble sleeping, anger, or even homelessness—this resource can support you. The Veterans Crisis Line is confidential (private), free, and available 24/7. **To connect with a Veterans Crisis Line responder anytime, day or night:** Call 800-273-8255, then select 1. Or text 838255 for a confidential **Veterans Chat.**

If you don't have an emergency, but you're not sure what type of care you need, call your nearest VA health facility:

**Chalmers P. Wylie VA Ambulatory Care Center** (Central Ohio)
420 N. James Rd Columbus, OH 43219 614-257-5200 | 888-615-9448

**Chillicothe VA Medical Center**
17273 State Route 104 Chillicothe, OH 45601 740-773-1141 | 800-358-8262

**Cincinnati VA Medical Center** (Southwest Ohio)
3200 Vine Street Cincinnati, OH 45220 513-861-3100

**Dayton VA Medical Center**
4100 W. Third Street Dayton, OH 45428 937-268-6511 | 800-368-8262

**Louis Stokes Cleveland VA Medical Center** (Northeast Ohio)
10701 East Boulevard Cleveland, OH 44106 216-791-3800 | 877-838-8262

Or search Ohio VA centers online at:
https://www.va.gov/directory/guide/state.asp?STATE=OH&dnum=ALL

## 9. What are the costs of taking part in this study?

The cost of all procedures associated with the study will be covered by the program sponsor, the Ohio Department of Mental Health and Addiction Services.

If you receive a bill associated with any labs or other services, this is an error. Please give it to the study coordinator who will resolve it for you.

## 10. Will I be paid for taking part in this study?

No. You will receive wearable fitness trackers that you can take home and use for the duration of the study. You will receive standard of care behavioral health and wellness therapies and snacks after treatment. You will not receive any other compensation for your time. No bio-specimens (blood samples) collected through this research will be sold or used to make new products or technologies.

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

If you suffer an injury through participation in this study, you should notify study staff immediately, who will determine if you should obtain medical treatment at a local urgent care or emergency department. The cost for this treatment will be billed to you or your insurance. You may notify the RN Case Manager, Joann Jessop at 614-344-6021.

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

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue in the study. By signing this form, you do not give up any personal legal rights you may refuse to participate in this study. An Institutional Review Board (IRB) responsible for human subjects' research reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and BEP Medical Group policies designed to protect the rights and welfare of research participants.

## 13. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, they may be used by other researchers working on related brain stimulation, mental health, or Veterans research without your additional informed consent.

## 14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released, for example, if required by state law.

Also, your records may be reviewed by the following groups:

- The US FDA, the Department of Health and Human Services (DHHS) Office for Human Research Protections, or other regulatory agencies;
- The WCG IRB;
- The sponsor supporting the study, their agents or study monitors;

- JLC Services, Inc., the contractor handling payment for eTMS services;
- Your insurance company (if non-study charges are billed to insurance, e.g., for urgent care visits).

If we find information that significantly impacts your health, we will share it with you during follow-up visits with clinic doctors and nurse practitioners. The types of research results that will be shared include abnormal lab values or other medical conditions that require treatment, e.g., low testosterone hormone level.

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.

## 15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

### I. What information may be used and given to others?

- Past and present medical records;
- Research records and records about your study visits;
- Records about phone calls made as part of this research;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - Reportable infectious diseases
  - Physical exams, laboratory, x-ray, and other test results
  - Diaries and questionnaires
  - The diagnosis and treatment of a mental health condition
- Records about the study device

### II. Who may use and give out information about you?

Researchers and study staff.

### III. Who might get this information?

- The sponsor of this research, meaning any persons or companies that are working for or with the sponsor or owned by the sponsor.
- Authorized research staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent medical record;
- Others: The State of Ohio Department of Mental Health and Addiction Services, BEP Medical Group Data Safety Monitoring Board and authorized clinicians on your care team.

## IV. Your information <u>may</u> be given to:

- The US FDA or DHHS agencies and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases must be reported; and
- State of Ohio Department of Mental Health and Addiction Services, for research oversight and approval.

## V. 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.

## VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely; the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

## VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. 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 researchers. 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.

## VIII. 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 or receive research-related treatment; however you will still be able to receive clinical care as a BEP Medical Group patient.

## IX. 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 consent. Any shared information may no longer be protected by federal privacy rules.

## X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

## 16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, if you feel you have been harmed, or if you need to report an injury as a result of study participation, contact Dr. Marcia Bockbrader at 614-670-4000 or by email at: dr.marcie@bepmedicalgroup.com.

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact the BEP HIPAA Privacy Officer by phone at: 614-670-4000 or by email at: neil@bepmedicalgroup.com. For questions about your rights as a participant or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Dr. Rick Massatti at Richard.Massatti@mha.ohio.gov.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

## Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions, have had them answered to my satisfaction, and I voluntarily agree to participate.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

| | |
|---|---|
| **Printed name of participant** | **Signature of participant** |
| | **AM/PM** |
| | **Date and time** |

**Investigator/Research Staff**

I have explained the research to the participant before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant.

| | |
|---|---|
| **Printed name of person obtaining consent** | **Signature of person obtaining consent** |
| | **AM/PM**<br>**Date and time** |

**Witness(es) -**

| | |
|---|---|
| **Printed name of witness** | **Signature of witness** |
| | **AM/PM**<br>**Date and time** |
| **Printed name of witness** | **Signature of witness** |
| | **AM/PM**<br>**Date and time** |