Date: 16 Mar 2026 (IRB approved Informed Consent)

TITLE: A Single-Blind Randomized Clinical Trial to Evaluate the Efficacy of High Vector Electrokinetics (HiVE), A Form Of Peripheral Magnetic Stimulation, In Treatment Of Chronic Back Pain

NCT Number Pending

DAVID GRANT USAF MEDICAL CENTER
CONSENT TO PARTICIPATE IN RESEARCH &
AUTHORIZATION TO USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

PRINCIPAL INVESTIGATOR: Joshua C. Ford, joshua.c.ford21.mil@health.mil, 661-275-5057

KEY INFORMATION FOR PROTOCOL: A Single-Blind Randomized Clinical Trial to Evaluate the Efficacy of High Vector Electrokinetics (HiVE), A Form Of Peripheral Magnetic Stimulation, In Treatment Of Chronic Back Pain

You are invited to take part in a research study. Your participation is voluntary. This page gives you key information about the study to help you decide whether to participate. Detailed information follows this page. Ask the researchers questions you have. If you have questions later, the contact information for the research investigator is below.

WHAT ARE THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn a new way to treat back pain without the use of medications. We plan use Transcranial Magnetic Stimulation (TMS), a wand-like device, to stimulate (excite) the nerves of your back in the area of your back pain to decrease pain and improve your ability to do daily activities. This study will have two groups and you will be randomly assigned (like flipping a coin) to a group. One group will have their back nerves stimulated with the TMS device and the other group will not. You will also need to do back exercises at home once a day, and complete questionnaires at each visit before and after each treatment. Your participation in this research will include 5 to10 visits with one visit occurring each weekday and each visit lasting up to 30 minutes.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO PARTICIPATE IN THIS STUDY (BENEFITS)?

The possible benefits to you from participating in this study include reduced lower back pain, learning about other treatments for back pain that do not involve using medication, improving your ability to do everyday tasks, and getting info on common exercises that can be done at home to help your low back pain. Your participation in this study may help advance scientific research, progress medicine, or discover a new treatment option that would be easy for Aircrew to do without medication. Additionally, you will still be able to continue therapies to make our back stronger and take pain medication (i.e., Tylenol, ibuprofen) for your back pain if you are assigned to the sham group (no nerve stimulation). However, there is no guarantee that you will benefit from being in this research.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE NOT TO PARTICPATE IN THIS STUDY (RISKS AND ALTERNATIVES)?

You may choose to not participate because you may not get nerve stimulation until after you complete the sham treatments, have partial improvement or more back pain, get skin burns or injuries from the probe. Additionally, someone might get your private information, or you could have concerns about your unborn child if you get pregnant while you are in the study.

If you choose to take part in this study, there is a risk that you may be in the sham group and receive no magnetic nerve stimulation and not receive any potential benefit if it is found that the magnetic nerve stimulation treatment is effective in decreasing pain, until after you complete the 5 sham treatments. You may not have any improvement in your back pain symptoms, have more pain during or after treatment, get skin burns if the probe is too hot, or injured if the probe is accidentally dropped on you. Additionally, financial strain from lost work hours to be in the study may be a risk

Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

There may also be other risks of taking part in this study that we do not yet know about.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have at David Grant Medical Center if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?

The person in charge of this study is Joshua C. Ford. If you have questions, suggestions or concerns about the study, his contact information is: 661-275-5057, 412th Medical Group, 30 Nightingale Rd. Edwards AFB, CA 93523.

If you have any questions about your rights as a research subject or if you have concerns or complaints about the research, please contact the Madigan Army Medical Center IRB Office at: 253-968-3524, Department of Clinical Investigation, 9040 Jackson Avenue, Tacoma, WA 98431-1100.

Please tell the researchers if you are taking part in another research study.

If you decide to take part in this research study, you will be asked to sign this document. Before you sign this document, be sure you understand what the research study is about in all sections of the consent form, including the risks and possible benefits to you.

DETAILED CONSENT:

1. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you are 18-64 years old and have had back pain for more than 12 weeks. The purpose of this research study is to learn about magnetic nerve stimulation and if it can help treat back pain. We believe that magnetic nerve stimulation may improve pain symptoms. Nerve stimulation using electricity and needles is a relatively common medical procedure. This study will use magnetic stimulation at a certain level to see if it has the same or better effect at decreasing back pain. This treatment has been used to treat back pain in the past but the frequency level we are testing has not been well-studied before. This means that the HiVE treatment protocol is still considered to be experimental for the treatment of lower back pain.

Your participation this study will include 5-10 visits one visit per day on weekdays. Each study visit will last up to 30 minutes and will include TMS treatment (2-3 minutes) and completion of questionnaires (12-30 minutes) before and after treatment.

There will be about 88 people taking part in the study from Edwards AFB and Luke AFB over a period of 6 months.

At the end of this study the clinical results, including research results about you will be shared with you if you desire. You will be told what study group you were in and your responses to the questionnaires you completed before and after your treatments will be shared with you. If you were in the sham group, you will be offered five magnetic nerve stimulation treatments if you desire.

2. SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY

Before you can take part in this study, you will need to have some tests and provide some information so that the Investigator can confirm that you qualify for the study. This is called the “Screening Process”. These tests may have been done or this information collected as a part of your regular medical care.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You will meet with a study investigator to review and sign this consent form. After signing this form, you will be enrolled into the study.

You will need to take a urine pregnancy test (it will be ordered by an investigator) if you are a female capable of getting pregnant to make sure you are not pregnant.

Next you will be randomly assigned to one of two groups. Randomization is a process like flipping a coin and means you will have an equal chance (50/50) of being assigned to one of two study groups:

- Magnetic nerve stimulation treatment group (experimental) will be conducted using a plastic wand that contains a magnet inside of it that will send out a strong magnetic field as it passes over your lower back region where you have the most pain which could cause the muscles in your back to relax and hopefully reduce pain.

OR

- No nerve stimulation treatment group (sham) will be conducted using a plastic wand that contains a magnet inside of it that does NOT send out a strong magnetic field as it passes over your lower back region where you have the most pain.

This research study is a single blind study, which means that you will not know whether you are receiving the magnetic nerve stimulation treatment or sham treatment. In the event of an emergency, the investigators can let you know which one you are receiving.

You will be scheduled for 5 treatment visits, experimental or sham based on the study group you are randomized to, and you will return daily to the physical therapy clinic at Edwards AFB for each visit. You will also be given a handout on back exercises to do at home every day while you are in the study. You will be asked to keep track of the number of sets of each exercise you do as well as the days you do the exercises. You will also be asked not to start any other back pain treatments such as new medications or join other research studies while you are in this study.

Each visit will include treatment which may last up to 3 minutes. During the treatments, you may be asked to lay on your front while a plastic wand that contains a magnet inside of it pass over your lower back region where you have the most pain. You will also be asked to complete questionnaires before and after each treatment asking you about your level of back pain, how your back pain affects daily activities, and how often you complete your back exercises, and how many sets of each exercise you completed at home.

After you complete your fifth treatment visit, your participation in the study will be complete unless you are in the sham group. If you are in the sham group, you may choose to have 5 magnetic nerve stimulation treatments. If choose to have these additional 5 treatments, you will return daily to the same physical therapy clinic at Edwards AFB for the magnetic nerve stimulation treatments. You will also be asked to complete questionnaires asking you about your level of back pain, how your back pain affects daily activities, and how often you complete your back exercises and how many sets of each exercise you complete at home.

After you have competed all 10 treatments (5 sham and 5 magnetic nerve stimulation treatments), your participation in the study will be complete.

4. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you are a FEMALE ABLE TO BECOME PREGNANT and you want to take part in this study, you should know that magnetic nerve stimulation of the lower back might be harmful to an unborn child if you are pregnant because it can cause your uterus to contract (like contractions in labor). You will take a pregnancy test before you can participate in this study. You should not get pregnant while in this study. The only completely reliable methods of birth control are not having sex or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy.

If you become pregnant or feel you might be pregnant, contact your personal physician and the principal investigator of this study listed in the Contact Information section at the end of this document.

5. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

There may be other options for treating your chronic back pain. Alternative treatments and/or procedures that may be available to you include: dry needling (use thin needles that do not have medication in them to treat back pain symptoms), massage therapy, cognitive behavioral therapy (teach you to change how you respond to your back pain symptoms), heat therapy, physical therapy, acupuncture (put thin needles into specific areas on your skin to stimulate nerves and muscles to treat your back pain symptoms) , surgery, nerve ablation (a procedure that destroys nerves in the area of your back pain), injection therapy (give you shots with medication in the area of your back pain to treat your symptoms), medications, or electrical nerve stimulation (a procedure that uses an electrical current to treat your back pain). You should talk with your personal physician about these options. There may be other research studies involving experimental treatments that could be helpful to your condition. Choosing not to take part in this research study is also an option.

6. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

No, you will not receive any compensation for participating in this study.

7. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

Yes, there are costs to you for taking part in this research study. These include any travel costs or lost income from time off work to participate in the study. You will not be reimbursed for these costs.

8. **PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):**

Joshua C. Ford

9. **STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):**

The study is sponsored by the 711th Human Performance Wing, Studies and Analysis Intermural 230 Research Fund.

As the sponsor of this research, the Department of Defense may have access to your research data in accordance with DoDI 3216.02.

10. **SOURCE OF FUNDING:** 711th Human Performance Wing, Studies and Analysis Intermural Research Fund.

11. **LOCATION OF THE RESEARCH:** 412th Medical Group, Edwards AFB, CA 242

12. **DISCLOSURE OF FINANCIAL INTERESTS AND OTHER PERSONAL ARRANGEMENTS**: None

13. **WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?**

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations. DD Form 2005, Privacy Act Statement - Military Health Records, contains the Privacy Act Statement for the records. A copy of DD Form 2005 can be given to you upon request, or you can read on-line at: http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2005.pdf.

The research team will keep your research records. These records may be looked at by staff from David Grant Medical Center (Travis AFB), the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to: Use of subject ID instead of personal identifiers, data resulting from your participation in the study will be documented in your electronic medical record and some will be coded and maintained within encrypted files and stored on CAC-enabled government computers and networks. Hard copy records will be secured in locked cabinets only accessible to the study team. Original signed hard copy consent forms with HIPAA will be stored separately from other study documents. Electronic records

are secured via DoD Microsoft Teams pages locked and only accessible to study personnel by invitation. At the conclusion of the study, all documents (hard, electronic) will be maintained for at least six years then destroyed by shredding, deleting file/folder from a secure drive and/or the cloud.

Researchers will make every effort to protect your privacy and confidentiality; however, there are risks of breach of information security and information loss.

Complete confidentiality cannot be promised for military personnel, because information regarding your health may be required to be reported to appropriate medical or command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

Only those study team members approved by the IRB will have access to your records and agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified; all information will be presented as anonymous data.

14. AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR THIS RESEARCH:

You are being asked for permission to use and disclose your protected health information (PHI) for this research study. Protected health information is defined as individually identifiable health information.

The Health Insurance Portability & Accountability Act of 1996, Public Law 104-191 (also known as HIPAA), establishes privacy standards to protect your health information. This law requires the researchers to obtain your authorization (by signing this document) before they use or disclose your protected health information for research purposes in the study listed above.

WHAT PERSONAL IDENTIFIERS AND/OR PROTECTED HEALTH INFORMATION (PHI) MAY BE USED AND DISCLOSED IN THIS RESEARCH?

The identifiers and/or PHI collected, used, or disclosed are below:

• *Names* • *Dates (except year) directly related to an individual such as birth date* • *Phone numbers*	• *E-mail addresses* • *Medical record numbers*

HOW WILL YOUR PROTECTED HEALTH INFORMATION BE USED OR DISCLOSED IN THIS RESEARCH?

Your name and date of birth will be used to access your medical record. Medical, surgical and medication history, imaging results (x-rays, CT scans, MRI) and pregnancy test results for women who are able to get pregnant will be reviewed in your medical record to ensure that you are eligible to join the study. Your phone number and email address will be used to schedule and coordinate study visits.

The use and disclosure of your protected health information is necessary in order to be able to conduct the research described. Records of your participation in this research may only be disclosed in accordance with state and federal law, including the Privacy Act (5 U.S.C. 552a) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations (45 CFR 160 & 164).

Note: Protected health information of military service members may be used or disclosed without your authorization to military command authorities to ensure the proper execution of the military mission, including evaluation of fitness for duty.

By signing this document, you give your permission for information gained from your participation in this research to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

WITH WHOM MAY YOUR PROTECTED HEALTH INFORMATION BE SHARED THROUGH THIS RESEARCH?

- The David Grant Medical Center Human Research Protections Program
- The Madigan Army Medical Center Institutional Review Board
- Madigan Army Medical Center or Department of Defense representatives
- State and Federal Government representatives, when required by law (such as the Food and Drug Administration (FDA))
- 711 Human Performance Wing Studies and Analysis Branch as program oversight

Those listed above who are covered entities under HIPAA agree to safeguard your protected health information by using and disclosing it only as permitted by you in this Authorization or as directed by state and federal law.

You need to be aware that some parties receiving your protected health information may not have the same obligations to safeguard your protected health information and may re-disclose your protected health information to parties not named above. If your protected health information is re-disclosed, it may no longer be protected by state or federal privacy laws.

You do not have to sign this document. If you decide not to sign this document:

- It will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- You will not be allowed to participate in the research.

After signing this document, you can change your mind and:

- Notify the principal investigator in writing that you have withdrawn your permission to disclose or use your protected health information (revoke the Authorization).
- Send your written letter to joshua.c.ford21.mil@health.mil, or Joshua C. Ford, 412th Medical Group, 30 Nightingale Rd, Edwards AFB, CA 93523 to inform him of your decision. Your revocation is not effective until your letter is received.
- Researchers may continue to use and disclose your PHI that was obtained before your revocation became effective to the extent that the researchers have taken action in reliance on your earlier authorization. Researchers may also continue to use or disclose your PHI as necessary to maintain the integrity or reliability of the current research, such as, for example, to account for your withdrawal from the study, to conduct misconduct investigations, or to report adverse events.
- If you withdraw the Authorization, you will not be allowed to continue to participate in the research.

During your participation in this research, you will not be able to access your research records. This is done to ensure the research results are reliable. After the completion of the research, you have the right to see or copy your research records related to the research listed above. A Request for Access must be made in writing to Joshua C. Ford, 412th Medical Group, 30 Nightingale Rd, Edwards AFB, CA 93523.

If you have not already received a copy of the brochure entitled “Military Health System Notice of Privacy Practices,” you may request one, or it is available on-line at: https://www.health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/HIPAA-Compliance-within-the-MHS/Notice-of-Privacy-Practices

If you have any questions or concerns about your privacy rights, you should contact the DDGMC HIPAA Privacy Officer, 101 Bodin Circle, Travis AFB, CA 94535. Telephone: 707-423-7916.

This Authorization does not have an expiration date.

Your signature at the end of this document acknowledges that you authorize David Grant 409 Medical Center and the study team members to use and disclose your Protected Health Information (PHI) collected about you for research purposes as described above.

15. INCIDENTAL FINDINGS

There is a possibility that while reviewing your test results we may see an abnormality that we did not expect to see in this study. This is what is called an "incidental finding."

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by phone. In the case of a potential serious emergency, the researcher will inform you right away.
We will also give information about this incidental finding to your primary care doctor, or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious
- Since an incidental finding will be part of your medical record, you could face greater difficulty in getting health or life insurance

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility. If you are a DoD beneficiary, you will have access to care through standard Military Health System and TRICARE procedures.

You may always view your medical information including any incidental findings, if found, in your electronic healthcare record via the MHS Genesis patient portal or contacting your local military treatment facility medical records section.

16. VOLUNTARY PARTICIPATION

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

17. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

Should you choose to withdraw, you must tell the investigator-person, by phone or email. You are not required to return any study documents you may have such as the home exercise guide. Stopping study treatments are not known to have any lasting side effects. If you decide to no longer participate in this research study, the researcher will keep any of your data that was already collected as part of this research study.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization section of this form.

The principal investigator of this research study may terminate your participation in this research study at any time if he determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

18. WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

CONTACT INFORMATION:

Principal Investigator (PI)

The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Joshua C. Ford
Phone: 661-275-5057
Mailing Address: 412th Medical Group, 30 Nightingale Rd, Edwards AFB, CA 93523

Madigan Human Research Protection Program (HRPP) Office

The Human Research Protection Program Office staff and/or Human Protections Director (HPD) will be available to answer questions or discuss concerns you may have about this research study. Please contact the 60 MDG HRPP Office at: 707-423-7209, Clinical Investigation Facility/SGSE, 101 Bodin Circle, Travis AFB, CA 94535 or usaf.travis.60-mdg.mbx.60mdg-cifprotocoloffice@health.mil .

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, ASK THE INVESTIGATOR BEFORE SIGNING. YOU MAY CONSULT WITH YOUR PERSONAL PHYSICIAN OR LEGAL ADVISOR, IF YOU WISH.

SIGNATURE OF PARTICIPANT

By signing below, I agree that I have been provided time to read the information describing the research study in the consent form. The content and meaning of this information have been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

19. CALIFORNIA HEALTH & SAFETY CODE §24172

Experimental Research Subject's Bill of Rights

California law, under Health & Safety Code '24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This list includes the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.