VA Department of Veterans Affairs	VA RESEARCH CONSENT FORM

Subject Name:

Date:_____

Title of Study: Self-administration of Auricular Acupuncture Pilot Project

Principal Investigator: Brian L. James, MD VAMC: Chillicothe (538)

Consent Version Date: 08/02/2018

Last Four of SSN:_____

Sponsor Name: VHA

INVESTIGATOR INFORMATION:

Principal Investigator Name	Telephone Number	24 hr Emergency Contact
Brian L. James, MD	740 773 1141 7639	911

INTRODUCTION:

Before you agree to take part in this research study, you should be told the purpose, procedures, benefits, risks, discomforts and precautions of the research. You should also be told what other procedures are available if you do not participate in the study.

Your participation in this research study is entirely up to you. If you decide to participate, you are free to withdraw your consent and to stop taking part at any time without unfairness to you or your medical care. The study doctor(s) do not promise that you will receive any benefits from this study.

This informed consent document is a brief summary of what your study doctor is telling you. Be sure to ask questions while you read this if there is anything that is not clear. You are always welcome to call and ask questions at any time.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?

We invite you to take part in this research study because you have chronic pain and Battlefield Acupuncture (BFA) has already worked well for you. As you know, chronic pain is difficult to treat and affects your life greatly. It is often treated with medications, which may have side effects that are harmful. BFA was created as an alternative to medications and is used in the VA and Department of Defense

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systems. You are invited to participate in this study because you have reported a good response to it that lasted at least three days.

To take part in this study, you must be willing and able to put the acupuncture needles into your own ears and not have someone else do it for you. This is for legal and safety reasons and cannot be avoided. Everyone who has had a good response to BFA is invited to participate except for those with certain medical conditions. The medical conditions that are too risky for use of BFA include: 1) those with replacement heart valves; 2) those with history of heart valve infection; 3) those who are pregnant. If you take blood thinners you may participate if you have had BFA before with no bleeding problems, as long as you know that you may be more likely to bleed from the procedure.

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?

Each person will take part in the research study for about six months. The entire study itself will take place over twelve months because not everyone will start at the same time. Again, you may leave or stop taking part in the study at any time.

Dr. James, Dr. Welch or Dr. Williamson may decide to take you off this research study at any time if there are medical concerns. BFA is considered a procedure of almost zero risk when performed by a trained provider. However, this study is looking at whether training people to perform BFA on themselves will have the same very low rate of complications as when a trained provider does it. So, it is possible that the study may be stopped early if more than a few people have issues with performing the procedure on themselves. Other problems that may cause the study to be stopped include a participant becoming seriously ill for other reasons, running out of resources to finish the study, or if research supervisors decide it is not safe to continue for any reason.

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You may be contacted in the future by representatives of the VA or University of Cincinnati who are interested in asking you survey questions about your participation in this research study. If you choose to participate in the survey, your responses will be used for quality assurance purposes

WHY IS THIS RESEARCH BEING DONE?

The main reason for this research study is to see if it is safe for veterans to give themselves BFA for their pain after getting trained by a provider. It is a simple procedure and does not require much knowledge of acupuncture or anatomy. We will also see if pain relief improves over time with repeated use of BFA.

Another thing we are trying to find out is if ear molds made with our 3D printer can help you place the needles correctly and easily. It may turn out that the ear molds do not help very much. Finding out how helpful the ear molds are is the second purpose of the study. However, it is definitely possible to put the needles in yourself without an ear mold to guide them.

Finally, if we see that there are very few side effects or problems when patients give themselves BFA, we will present our findings to higher levels in the VA system. We will propose a rapid expansion of this program to make sure everyone who wants BFA can get it. Some veterans need to travel a great distance to receive BFA and the main goal of this project is to make it easier for them to get it. The researchers also hope that letting people perform BFA on themselves might lead people to use fewer medications.

WHO IS CONDUCTING THE RESEARCH STUDY?

This study is sponsored by the Veterans Health Administration (VHA) VISN 10, which is the regional VA network that contains Chillicothe VAMC.

The study is directed by Dr. Brian James, a medical doctor at Chillicothe VAMC. Dr. Clint Williamson and Dr. John Welch, who are chiropractors at Chillicothe VAMC will also be working with Dr. James. Medical supervision for the study is provided by Dr. Brian James.

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Participants will be contacted by study personnel ONLY for the purposes of recruiting and collecting data directly pertaining to the study treatment. Non-study personnel may contact participants for scheduling of appointments but will not discuss any aspect of the research project or collect data.

Melissa Davis, a Chillicothe VAMC recreational therapist, will be working with veterans to create their ear molds. None of the research team owns stock or has a financial interest in any of the companies involved in making the acupuncture needles, 3D printer or printing materials.

HOW MANY PEOPLE WILL TAKE PART IN THE RESEARCH STUDY?

About 30 to 40 people will take part in this study at Chillicothe VAMC. These people will be veterans who receive care at the main Chillicothe VAMC facility and any of its community-based outpatient clinics (CBOCs) such as those in Lancaster, Wilmington, Marietta, etc.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

1. People who choose to be in the study will be trained to insert the BFA needles into their own ears. Training will be done by either Dr. James, Dr. Welch or Dr. Williamson over the course of an hour. The time allowed for training may be adjusted if needed. Everyone is welcome to call and ask for more guidance if needed.
2. Participants will receive handouts with the BFA protocol for reference on exactly how to place the needles. This handout includes the points to needle, how often to needle and other information.
3. A silicone ear will also be given to practice on. Participants will be given an 80-count box of ASP Gold ear acupuncture needles along with a supply of alcohol pads to clean the ears. This should last AT LEAST sixteen weeks or four months if the proper BFA protocol is used.
4. After the training, an appointment will be made to make ear molds that you wear over your ears. These will help guide the needles into the correct places. The ear molds may be pre-made or they may require a 3D scan to provide a customized fit. This scan uses ultrasound and does not involve any radiation like an X-ray or CT scan.

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5. You will begin using the needles on yourself before you get the ear molds. That way you can tell us if the ear molds are helpful for placing the needles.
6. The ears will be cleaned with alcohol pads before each insertion of the needles.
7. Needles will be self-inserted by study participants about every two weeks following the BFA protocol
8. One of the study personnel with appropriate scope of practice will call the participants about every two weeks to find out how the acupuncture is working and whether there are any problems. There is a standard “note” for BFA in our computer system and that will be used. Participants may be asked to keep a log of specific questions so they can document their immediate response to BFA so they won’t forget when they are called.
9. The research staff will take your answers and put them into a medical progress note that is designed to be used with Battlefield Acupuncture.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

It is EXTREMELY important that the needles are used BY YOU, ON YOURSELF ONLY. In other words, NO ONE EXCEPT YOU should be inserting the needles in YOUR OWN ears. Also, BFA needles given during the study should NEVER be used on anyone except YOURSELF. If these rules are not followed, you will be asked to stop participating in the study and to return the needles and ear molds.

Serious side effects from BFA are *extremely* rare. The VA considers BFA to have almost zero risk when done correctly by a provider. It does not require a written consent form in the VA because it is extremely low risk. However, this study cannot be considered “minimal” risk for research purposes. This is because there is the possibility for more harm than would be expected from someone looking at your records or a routine physical exam.

The most common side effect that is expected is temporary discomfort in the ears after insertion of the needles. Feelings of tingling or warmth around the area can happen sometimes but these usually go away quickly. Small scrapes can also occur if the needle applicator is angled while inserting it. Minor bleeding is

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also possible. Rarely, dizziness or nausea occur. Dizziness and nausea are very unlikely to happen if they did not happen when participants got BFA from the provider. Since almost everyone in this study will have had multiple BFA sessions by a provider, we expect a very low or zero rate of these common side effects.

The needles used in this study are ASP Gold needles. Each needle comes in a sterile container with a sterile plastic applicator to help insert the needles. These needles are called “semi-permanent” or “indwelling” acupuncture needles because they are designed to stay in the skin and not come out easily like regular acupuncture needles. They are much smaller than regular acupuncture needles and do not stick out much. It is thought that letting them stay in like that extends the pain relieving effect. They are also designed not to go too deep in the skin. If they are used with the applicator and only on the ear like they should be, it is almost impossible for them to go too deep into the skin. The ASP needles usually fall out on their own after several days but some people’s skin will allow them to stay in much longer. Per the BFA protocol, the needles must not be left in for more than seven days. Do not try to make them stay in longer than that. After they fall out on their own or after removal, they should be thrown in the trash. They should not be reused and are very difficult to insert without the plastic applicator that comes with each needle. The plastic applicators should also be thrown away and should not be reused.

Sometimes the needles will fall out without you being aware of it. This usually happens at night when your head is on the pillow. It may not be possible to find the needles when this happens, especially if they sink into the carpet or into small cracks. Extra caution must be taken by the participant if small children and animals are around. While it is unlikely that serious harm will be caused by these needles, it is remotely possible, so the participant should take every step possible to minimize accidental injury to others.

Infection of the skin and ear is possible but very unlikely if the ears are cleaned and the needles are looked at regularly in the mirror. It is important to make sure that the needles do not stay in for longer than seven days at a time to avoid infection or the needle getting buried in the skin. The needles are designed to avoid getting buried in the skin, but if they stay in too long it is possible that the skin will grow over them.

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Skin irritation and scarring from needle insertion can occur but is very rare. The BFA protocol tells you not to put a needle in the same spot more than once every two weeks. Do not put a needle in the same spot in your ear more than once every two weeks or it can irritate your ears and make it painful to use BFA. Even if the needles fall out early, do not put one in the same spot more than once every two weeks.

For participants who are on blood thinners, there is an increased risk of bleeding with insertion of the needles. However, too much bleeding is rare with BFA even if someone is on blood thinners. If you are on a blood thinner, you can participate in this study if you accept the risk of increased bleeding.

The worst problem that can happen from using indwelling needles is infection of the heart valves. This is a serious complication that can lead to death or severe disability. The only known cases of heart valve infections were in people who had replacement heart valves or had already had an infection of their heart valves. Overall, the chances of this happening to someone without heart valve problems is probably less than “one in a million” or almost zero. Let Dr. James, Dr. Welch or Dr. Williamson know if you have a replacement heart valve or if you have had an infection of your heart valves, even as a child. This also includes having rheumatic fever as a child.

WHAT ARE THE RISKS OF STOPPING YOUR CURRENT TREATMENT?

There are no known risks of stopping treatment with BFA. The only thing expected to happen is that you will no longer get pain relief from BFA.

WHAT ARE THE REPRODUCTION RISKS?

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There are no known reproduction risks associated with BFA. However, traditionally it is avoided in pregnancy because of concerns it might trigger labor or harm the baby. Dr. James does not wish to cause any harm to pregnant women or their unborn children so women who are pregnant will not be included in this specific study. Women who participate who are trying to become pregnant or become pregnant during this study will be asked to stop to avoid risk to the pregnancy.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

If you agree to take part in this research study, there may not be a direct medical benefit to you. However, you were invited to take part in this study because you already had a good response to BFA that lasted at least a few days at a time. It is expected that BFA will continue to work for you if you give it to yourself. The investigators hope the information learned from this research study will benefit other patients with chronic pain in the future. Potential benefits to you may include 1) the ability to use BFA without having to travel to a VA clinic or hospital; 2) being able to lower the amount of pain medications you take; 3) improving your pain over time; and 4) having a stronger sense of control over your pain.

WHAT OTHER CHOICES FOR CARE ARE THERE?

Instead of being in this research study, you have these options:

1. Receiving BFA from a provider.
2. Another of the other standard methods of treating pain that are used commonly.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Every effort will be made to maintain the privacy of your study records. The Department of Veterans Affairs, and the University of Cincinnati, and any sponsoring company will be allowed to inspect sections of your medical and research records related to this study. The data from the study may be published; however, you will not be identified by name. Your identity will remain confidential unless disclosure is

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required by law. Destruction of all research records pertaining to this study will be in accordance with the Department of Veterans Affairs record retention schedule.

Your data and files will be secured in the Computerized Patient Record System (CPRS), which is the electronic medical record system used by VA. To access this information requires an ID card, a PIN number, a username and a password. It is considered very secure and the data will be stored in the local database. The only two things that will not be stored in the computer system will be: 1) a list of participants that has their initials and last four of their SSN and 2) the written informed consent forms. Both will be kept in a locked cabinet inside a locked room. Only people directly involved in the study will have access to these. VA sensitive data will not be removed from the VA environment. Mobile storage devices will not be used to store data related to this study.

Your data will be kept confidential. The data used in the study will not include any information that can directly or indirectly identify you. The main source of our data that will look at will be “Battlefield Acupuncture” notes in the computer, which are already used when a provider does this procedure. Your data will only be released according to the rules of VHA and the federal government. We do intend to publish our results, but nothing that can identify you will be included in this publication.

Data will be kept for the appropriate time period required by the federal government. The source of the data will be clinical notes in the medical record system that are a permanent part of the medical record. It is possible that further research may be done with this data, but this will not require you to become involved and will be subject to strict oversight by regulating agencies involved in supervising research. Your confidentiality and privacy will be protected at all times. After the appropriate time period according to federal law, any additional paper copies of sheets such as informed consents and de-identified lists of participants will be destroyed by HIPAA-compliant shredding. Access to study data will be revoked from study personnel if they are no longer participating in this research project.

WHAT IS THE CLINICAL TRIALS REGISTRY?

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A description of this clinical trial will be available on 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.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?

Your costs may include travel to and from the VA facility initially for the training part of this study and for any needed follow-up appointments such as for making the ear molds or if you request more training. You will receive the BFA needles, ear molds and educational materials free of charge. One 80-count box of BFA needles should last AT LEAST sixteen weeks if the proper BFA protocol is followed.

Department of Veterans Affairs patients may be financially responsible for care at the Department of Veterans Affairs. Financial responsibility is individually determined based upon legislative criteria. Some veterans are required to pay co-payments for medical care and services; these co-payment requirements will continue to apply to medical care and services provided by the Department of Veterans Affairs that are not part of this study.

WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?

This study does not include any money payment for participation. You will receive all supplies and training free of charge. Reimbursement for travel to the facility to receive these items is not automatically guaranteed unless you are normally eligible for them and they are allowed for research activities.

WHAT COMPENSATION IS AVAILABLE IN CASE OF INJURY?

The Department of Veterans Affairs will provide necessary medical treatment to you as a research subject if you are injured by participation in this research project, at no cost to you. This requirement does not

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apply to treatment for injuries that result from non-compliance by you with study procedures. The Department of Veterans Affairs does not normally provide any other form of compensation for injury. You have not released this institution from liability for negligence.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you. The investigators will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers. You are welcome to call our research staff at any time with questions.

Nothing in this consent form removes any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?

If you have any questions regarding this study, if you experience side effects or to report a research-related injury or illness, or if you have any additional concerns, complaints and/or suggestions while you are participating in this study, you can contact Dr. James at 740-773-1141 x7639.
Please call the University of Cincinnati Medical Institutional Review Board at 513-558-5259 (Monday – Friday 8 am to 5 pm) if you:

- Think the research has hurt you.
- Have general questions about giving consent or your rights as a research participant in this research study.

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- Have questions, concerns, or complaints about the research.
- Cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.

If you want to check to be sure this study is approved and the researchers are authorized to do this study please contact the Cincinnati Department of Veterans Affairs Research Service at 513-475-6328. Information can also be found at the internet at http://www.clinicaltrials.gov

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INVESTIGATOR INFORMATION:

Principal Investigator Name	Telephone Number	24 hr Emergency Contact
Brian L. James, MD	740-773-1141 x7639	911

SIGNATURES

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. I have received answers to my questions. If I do not participate or if I discontinue my participation, I will not lose any benefits.
I will not lose any legal rights if I discontinue. My participation in this research is completely voluntary. I give my consent to participate in this study. I have received (or will receive) a copy of this form for my records and future reference.

_____ _____

Participant Date

PERSON OBTAINING CONSENT:

I have reviewed this form with the participant and/or representative. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information.

_____ _____

(CVAMC02-2015)

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Signature and Title of Person Obtaining Consent and Identification of Role in the Study

Date

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