Participant Name _____Date:_____

Title of Study: Utilizing Battlefield Acupuncture (BFA) to treat chronic pain for homeless and at-risk Veterans

Principal Investigator: _Cathy St Pierre, PhD_ VA Facility: _VA Bedford Healthcare System_____

Sponsor of Study: National Center on Homlessness Among Veterans/Research_____

We are asking you to choose whether or not to volunteer for a research study. This consent form will give you information about the study to help you decide whether you want to participate. Taking part in this study is completely voluntary. This project hopes to enroll 35 participants.

SUMMARY OF IMPORTANT INFORMATION

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

1. WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This study is examining the effects of Battlefield Acupuncture on chronic pain. This study will also evaluate the impact, if any, that treating chronic pain may have on behavioral health factors such as anxiety, depression, substance use, housing stability and physical health. It is being funded by the National Center on Homelessness among Veterans within the Department of Veterans Affairs. By doing this study, we hope to learn about the effect of Battlefield acupuncture on pain for Veterans.

The purpose of this research is to gather information on the effectiveness of these acupuncture treatments. We will be using ASP tacks, small gold needles, for the treatments. These tacks are produced in France and have been use for several years to treat pain. The treatment protocol for this study is consistent with the use of tacks needles and will not be deviating from the intended use of these tacks.

2. WHAT DOES THE STUDY INVOLVE AND HOW LONG WILL IT LAST?

Your participation in this research will last about 12 weeks. It involves receiving weekly Battlefield Acupuncture treatments and filling out questionnaires about your pain and its effect on your daily life. We will also ask questions about anxiety, depression,substance use and housing stability. A random subset of 12 participants will also be invited to be interviewed about their experience at the end of their treatment.

3. WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

It is possible that participating in this project will help you with your pain, and if effective, improve your quality of life. However, we can't guarantee that you will personally experience benefits from this study. Others may benefit from the information we find in this study.

4. WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You may experience pain from the Battlefield Acupuncture treatment. You may also find some of the questions that we ask to be upsetting. You can choose to withdraw from this study at any time by contacting a study staff member. There are other treatments for these conditions that you may use instead of receiving Battlefield Acupuncture.

5. DO YOU HAVE TO TAKE PART IN THE 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 if you choose not to volunteer.

6. WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Cathy St Pierre of the VA Bedford Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, her contact information is: 781-687-2983.

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS STUDY?

You are invited to participate in this research project designed to study the effects of Battlefield Acupuncture on chronic pain. You have been invited because you are homeless or at risk of being homeless and experiencing chronic pain.
With this research we hope to learn whether Battlefield Acupuncture is helpful for Veterans. We will be looking at the effects of Battlefield Acupuncture on pain, housing, behavioral health, substance abuse, and physical health.This treatment has been approved by the Food and Drug Administration for the specific use being evaluated in this project.

HOW LONG WILL I BE IN THE STUDY?

Your individual participation in the project will take 12 weeks. This research study is expected to take approximately 2 years.

WHAT WILL HAPPEN AND WHAT CAN I EXPECT IF I TAKE PART IN THIS STUDY?

If you take part in the study, you will have weekly study visits for 12 weeks at the VA Bedford Healthcare System.
On the first day, we will go through this consent document and you will fill out a questionnaire asking questions about your housing, behavioral health, substance use, and physical health. You are free to skip any question that you prefer not to answer. This will take 45-60 minutes.This part of the study will be coordinated by the Research Coordinator, Alexandra Howard and the Principal Investigator, Dr Cathy St. Pierre.

You will then receive your first Battlefield Acupuncture treatment which involves putting 3-5 tacks in both of your ears. These will be placed by Dr. St Pierre, a trained provider. After 3 tacks are place, you will be instructed to walk around and see if your pain level has changed at all. Once all 5 of the tacks are placed (initially in one ear and then if tolerated, both ears), you will again be asked to walk around and again asked if there is a change in your pain

level. You will be given an information sheet about BFA and what to expect after treatment. These tacks will stay in your ear until they fall out naturally, usually in a few days. You can take them out in three days if they have not fallen out by then. At the first visit, Dr. St Pierre will show you how to remove the tacks.

You will come back weekly after the first session. Each time, you will receive a Battlefield Acupuncture treatment and will fill out a questionnaire similar to the one you filled out on the first day, regarding your pain.. These follow up visits will take 15 -20 minutes. During these visits, we will check in with you to make sure you are not having any problems with the acupuncture.

For the duration of this study, we ask that you:

- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule. If you are unable to keep an appointment, contact the research staff to cancel.
- Tell the investigator or research staff if you believe you might be pregnant
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- While participating in this research study, do not take part in any other research project without approval from the investigators.Taking part in other research studies without first discussing it with the investigators of this study may invalidate the results of this study, as well as that of the other studies.

A subset of participants will be invited to be interviewed, either in person or by phone, about their experience at the end of their treatment. We will ask you specific questions about changes in your pain, behavioral health, and aspects of your life that may have been affected by your acupuncture treatments. We will also be asking for feedback regarding the BFA program. This interview is optional. These interviews will take up to 60 minutes.. The interviews will be audiorecorded in order to make sure we don't miss anything you said but you may request for the recording to be stopped at any time and it will be stopped. These audiorecordings may be shared outside the VA with a VA-approved transcription company

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS OF TAKING PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

1) Pain or bruising at insertion site.
2) Initial increase in chronic pain with resolution over hours/days.
3) Redness, bleeding or infection at site of insertion. You will be instructed on first visit to contact Dr. St Pierre for any problems.
4) Discomfort at site of tack insertion.
5) Questionnaires and interviews. Some people become uncomfortable at being asked questions about their health, substance use, and housing; 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.

The safe use of Battlefield Acupuncture in pregnant women 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. If, while participating in the study, you suspect you have become pregnant, please contact the study PI immediately. You will be withdrawn from the study. There is always a chance that any Battlefield Acupuncture can harm you. The Battlefield Acupuncture in this study is no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

If during the study, after completing the behavioral health questionnaires, if the PI has concerns regarding your responses (such as suicidal ideation or depression) , the PI will discuss them with you and help to coordinate further care from a behavioral health professional, if needed. Risks of the usual care you receive 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. It cannot be guaranteed that you will be able to continue receiving this procedure after this study is over.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

We do not know if you will get any benefits from taking part in this research study. However, possible benefits may include improvement in pain, behavioral health, physical health, substance use and/or your housing situation.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You may choose not to participate in this study. If this is your decision, there are other choices such as therapy, other medications, and using VA resources for homelessness. You may discuss these options with your doctor and other providers.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Participation in research may involve a loss of privacy. Your research records will be kept as confidential as possible. Only a code number will identify your research records. The code number will not be based on any information that could be used to identify you (for example, social security number, initials, birth date, etc.) The master list linking names to code numbers will be kept separately from the research data. All research information will be kept in locked files or behind the VA firewall at all times. Only study team members will have access to this data. If results of this study are reported in journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. All data will be kept in accordance with the VA record regulations.

We will include information about your study participation in your medical record. A medical record will be created if you do not already have one. Notes from your visits and procedures, will be included in this record. In addition to the research team, and the VA staff who provide clinical services, other researchers may be granted approval to access this information in the future. Federal laws and regulation that protect privacy of medical records will apply to your VA record.

Only authorized persons will have access to the information gathered in this study unless required by law. These are Dr. St Pierre and other members of the research team.
Other agencies who may have access to this data are: Federal Agencies such as the Office for Human Research Protection (OHRP), Government Accountability Office (GAO) and Food and Drug Administration (FDA) may have access to the records.
Your information collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of certain communicable diseases, physical or sexual abuse, child or elder abuse or neglect, or harm or risk of imminent harm to self or others. The Certificate does not protect you if you, someone in your family, or someone you know voluntarily releases information about you.

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

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You, or your insurance, will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.
If you are selected to take part in the interview and you choose to do so, you will be compensated for your time with a $25 CVS gift card that you will receive at the time of the interview. You will not be compensated for the treatments and surveys.

DO I HAVE TO TAKE PART IN THE STUDY?

Participation in this research study is voluntary. You may refuse to participate and your refusal to participate will involve no penalty or loss of benefits to which you are entitled. You may also discontinue participation at any time, without penalty or loss of benefits to which you are entitled, by letting a study team member know that you would like to withdraw from the study. For data already collected prior to the your withdrawal, we may continue to review the

data already collected for the study but we can't collect further information, except from public records, such as survival data
You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. Withdrawal from this study will not affect any of your VA care now or in the future.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION (Include if applicable)

Although not expected, if the researchers become concerned that somehow being in the study is harming you, due to adverse effects of the acupuncture or the questions, we may stop your participation, even if you do not agree. If we stop your involvement in the study, no additional data will be collected, but the data already collected may be used.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?
New findings that develop during the course of the research that may affect the your willingness to continue participation will be provided to you.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call Dr. St Pierre at 781-687-2983 during the day, and after hours call 781-687-2000 and have the doctor on call paged.

VA Medical Facilities shall provide, or arrange for, necessary medical treatment to a research subject injured as a result of participation in a research project. This does not apply to treatment for injuries due to non-compliance by the subject with the study procedures
No money has been set aside for compensation in case of injury as a result of participating in this study however I have been told that I would still have the right to file any legal action

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have any questions about the research, you may contact Dr. St Pierre at 781-687-2983.

If you have any questions, concerns, or complaints about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board Coordinator, Denise Carr at 781-687-2839, and the information will be given to the Institutional Review Board. This is the Board that is responsible for overseeing the safety of human participants in this study.

Participant Name _____Date:_____

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AGREEMENT TO BE AUDIORECORDED

□ I agree to be audio-recorded for the optional 30 minute interview
□ I do not agree to be audio recorded for the optional 30 miute interview

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms_____has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. A copy of the consent will be given to you.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date