KEY INFORMATION FOR ACUPOM (ACUPUNCTURE FOR PAIN, OPIOID USE DISORDER AND MOOD)

We are asking you to choose whether or not to volunteer for a research study about acupuncture, pain, opioid use disorder, and mood. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we are researching whether acupuncture could be helpful to patients like yourself with pain, opioid use disorders and mood symptoms.
If you participate, you will receive acupuncture in the ears for about 20-30 minutes, twice a week, for 4-5 weeks.
Acupuncture is treatment where small needles are use to target certain areas in the body.

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

Acupuncture is a type of treatment that has been used to treat a variety of conditions. By participating in this study you may find relief from conditions associated with pain, opioid use disorder and mood symptoms.
For a complete description of benefits, refer to the Consent Document below.

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

If you have a fear of needles may not want to volunteer for this study, but we will ensure that you are as comfortable and prepared as possible.
For a complete description of risks, refer to the Consent Document below.

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 or access to care you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Principal Investigator, Jessica Bayner, M.D. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is:
jbayner@montefiore.org and 718-920-4736.
If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einstein.yu.edu

ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called AcuPOM (Acupuncture for Pain, Opioid Use Disorder and Mood). Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator," Jessica Bayner, M.D. You can reach Dr. Bayner at: **Office Address: 111 E 210th Street** **City, State Zip: Bronx, NY 10467** **Telephone #: 718-920-4736** For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.	The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einsteinmed.edu, or by mail: Einstein IRB Albert Einstein College of Medicine 1300 Morris Park Ave., Belfer Bldg #1002 Bronx, New York 10461
Support for this research study is provided by the National Institute of Health and the Integrated Care for Chronic Pain and Opioid Use Disorder (IMPOWR) Research Center at Montefiore/Einstein (IMPOWR-ME).	

Why is this study being done?

The goal of this study is to determine how patients with chronic pain and opioid use disorder will respond to treatment with acupuncture, including whether there will be any changes in mood. Results from this study have the potential to inform future studies in patients who would consider using acupuncture as an intervention for their conditions.

Why am I being asked to participate?

You are being asked to participate in this study because you have a history of chronic pain and are in a methadone treatment at an opioid treatment program. You are not eligible if you have certain conditions that can make participation in acupuncture treatment difficult, hazardous, or unsafe, such as pregnancy, or having any other reasons that prevent you from being able to participate in the study.

What will happen if I participate in the study?

You will participate in acupuncture sessions that will last about 20-30 minutes, twice a week for 4-5 weeks. These acupuncture sessions will take place in a location within the clinic that is comfortable, in a seat that supports your back. During the procedure, your ear will be cleaned, and sterile, small acupuncture needles will be placed on areas of the ear that we believe target addiction and pain. The

needles we use are thin and very small, and should not cause a lot of discomfort. The needles will remain in your ear until the acupuncture session is completes.
After the session, there will be small balls called acupuncture seeds placed on your other ear. The seeds are attached using tape and are placed on areas we believe target addiction and pain. You will be instructed to push on the seeds between acupuncture sessions to see if they help you feel pain, cravings, and/or mood symptoms.

As part of this study we will review your medical records and put the information we collect in our research records. We will additionally give you questionnaires to fill out before and after your treatment (at baseline, in the middle and end of the study, and before and after sessions). We will also ask to record and transcribe your thoughts on the study at the end, using several short interview questions meant to reflect on your experience in this study.

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.

Genetic Testing

NO

This study will not involve genetic research or genetic testing.

Information Banking (Future Use and Storage)

Data Stored with Identification Linking Code

We will store information about you in a "bank", which is a library of information from many studies. This information can be linked to you. In the future, researchers can apply for permission to use the information for new studies to prevent, diagnose or treat disease, including genetic research. If you agree to the future use, some of your de-identified genetic and health information (not linked to you) may be placed into one or more scientific databases. These may include databases maintained by the federal government. Your information may be kept for a long time, perhaps longer than 50 years. You may remove your consent for future research at any time by contacting the Principal Investigator named on the first page of the consent or the IRB office at 718-430-2237. If you do, we will destroy the information in the bank but if the information was already shared with other researchers, we cannot get it back.

You can choose not to participate in the bank and still be part of the main study and this will not affect your treatment at this facility**.**

INITIAL ONE (1) OF THE FOLLOWING OPTIONS

_____ I consent to have my information used for future research studies.
_____ I do NOT consent to have my information used for future research studies. Information about me will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

INITIAL YOUR CHOICE BELOW

_____ I consent to be contacted in the future to learn about:
    _____ New research protocols that I may wish to join.
    _____ General information about research findings.
_____ I do not want to be contacted at all.

Will I be paid for being in this research study?

If you give consent and receive treatment you will be reimbursed $50 for your participation at the end of each study assessments after completing surveys. If you complete at least 50% of treatments, you will get an additional $50, for a total of $200.

If you choose to withdraw from the study before all visits are completed, you will be paid only for the study assessments you completed.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, medical record numbers, etc. In addition, the researchers wish to review information pertaining to your substance abuse treatment records and psychiatric treatment records. By law, you must specifically authorize access to these records:

☐ Yes, I authorize the use and disclosure of my information pertaining to substance abuse treatment.
Initial: _____ Date: _____

Your information and research records will be kept confidential. Your study information will be kept as long as they are useful for the research described in this form.

Your identifiers will not be stored and data will be coded to protect your confidentiality.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers
- Organizations and institutions involved in this research, including those that fund the research, if applicable
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information

may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

Medical information collected during the research, such as test results, may be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Are there any times you would not keep my data confidential?
If you give us information that suggests that your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.

If you give us information that you may hurt yourself, your confidentiality will be broken if interventions are needed to ensure your safety.

If you give us information that you may hurt someone else, we will break confidentiality and assess whether intervention in needed, including reporting information to the authorities.

Certificate of Confidentiality

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Are there any risks to me?

We do not think there are any major physical risks related to participating in this research study.
The Battlefield Acupuncture (BFA) protocol and the National Acupuncture Detoxification Association (NADA) protocol are two different approaches to auricular (ear) acupuncture that have been used to address pain management and addiction / substance abuse recovery. While ear acupuncture is generally considered safe when performed by a trained and licensed acupuncturist or healthcare provider, there are still some risks associated with the procedure, including infection, bleeding and bruising, pain and discomfort, allergic reactions, fainting or dizziness, nerve injury, and psychological sides effects (anxiety, and fear).

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not

supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

Questionnaire
You may feel uncomfortable answering questions about your pain, opioid use/cravings and mood symptoms. You can choose not to answer questions that make you feel uncomfortable.

Are there possible benefits to me?

You may or may not receive personal, direct benefit from taking part in this study. The possible benefits of taking part in this study include relief of pain, opioid cravings and withdrawal, and mood symptoms.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers and the sponsor may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Principal Investigator and she will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?

We will not let you participate in the study any more if you become pregnant. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

_____	_____	_____
Printed name of participant	Signature of participant	Date
_____	_____	_____
Printed name of the person conducting the consent process	Signature	Date