ALBERT EINSTEIN COLLEGE OF MEDICINE

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called "Assessing the Efficacy of Self-Driven Repetitive Artmaking on Pain and Mood States for Patients with Chronic Pain Opioid Use Disorder, and Opioid Misuse". 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 researchers in charge of this project are called the "Principal Investigators." You can reach them at:

Dr. Jenny Seham
Montefiore at 3340 Bainbridge Avenue
Bronx, NY 10467
jseham@montefiore.org
(718) 696-3011

For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

Support for this research study is provided by the **National Institutes of Health**.

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@einstein.yu.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Why is this study being done?

The goal of this study is to see if doing simple art projects at home can help people with chronic pain and opioid use disorder (OUD) or opioid misuse with their experiences of pain, depression, anxiety, and connection with others.

This study fills a gap in existing research into the utility of art for chronic pain and opioid misuse, which has exclusively looked at the ways in which art therapy is used in clinical and structured contexts. However, people living with chronic pain and OUD/opioid misuse may experience barriers to accessing clinical art therapy services – such as they are hurting too much to get to the clinic for in-person meetings with art therapists, or art therapy programs require certain levels of sobriety for participation. A project that explores whether making art at home can help lessen pain and negative moods (anxiety, depression) and improve feelings of social connection could help us understand whether this far cheaper method of art therapy practice would be useful for people living with chronic pain and OUD/opioid misuse.

The primary purpose of this study is to assess the acceptability of self-directed art making for people with chronic pain and OUD/opioid misuse, or to state it another way, whether people with chronic pain and OUD/opioid misuse will realistically do this artistic practice on their own.

A secondary question of this study is to explore whether doing this art practice can help minimize pain during the artistic process, lessen depression and anxiety, and improve feelings of social connection.

The third aim of the study is educational – to see if showing the art made by people living with chronic pain and OUD/opioid misuse lowers the stigma the general population may feel toward people living with chronic pain and OUD/opioid misuse.

Why am I being asked to participate?

You are being asked to participate in this study because you experience chronic pain and you either have a diagnosis of OUD or you have disclosed opioid misuse. To participate, you must also be at least 18 years old and fluent in either English, Spanish, or both. A total approximately of 40 people will participate in this study, with everyone recruited from 1250 Waters Place.

What will happen if I participate in the study?

If you participate in the study, you will be first asked to join a two-hour in-person art workshop. In this workshop, you will be taught how to use all three of the art kits we have created for this study, so that you feel confident exploring with them at home. In the workshop, you will also be given education for how to report your experience with the art kits through a brief survey tool, and you will be given the opportunity to use this tool in the workshop before you go home.

Next, you will be given a four-month period where you can use any of the art kits you want. During that time, you will be invited to use the art kit and complete the survey tool to report your experience for compensation for up to four times. One month after you attend the in-person workshop, you will receive a check-in call from the Study Coordinator who will ask you some brief questions to see whether you have used the art kits.

You will also be invited to participate in a two-hour discussion to talk about your experience with the art kits.

At the end of the four-month period, you will be invited to bring any of the art you have made to Montefiore to be professionally photographed for an art show. You will also be invited to share a short verbal story or explanation of the art piece, what it means to you, how it felt to make it, or anything you want to share. Whether you include your art in the show or not, you will be invited to attend the event.

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.

How many people will take part in the research study?

You will be one of approximately 40 people who will be participating in this study.

Will there be audio and/or video recording?

The meaning making session will be audio and video recorded on Zoom for the purpose of transcription. Faces may be identifiable in the video, but this video will only be used so that the researchers can create a written transcription – and then the video will be destroyed.

Genetic Testing

This study will not involve genetic research or genetic testing.

Information Banking (Future Use and Storage)

No Data is Stored

Information about you will be kept as long as required by regulations and institutional policy, but will not be used for future studies.

Will I be paid for being in this research study?

You will receive up to $180 in Clincard payments (like a Visa gift card) for participating in this study – $50 for participating in the in-person art workshop, $20 for each time you use an art kit at home and complete the survey tool for up to four times, and $50 if you participate in the meaning making session. A meal will also be provided at the art workshop. If you choose to withdraw from the study before all visits are completed, you will be paid only for the activities you completed.

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, social security number, medical record numbers, etc.

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.

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.

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 risks to me?

We do not think there are any physical risks related to participating in this research study.

Surveys
You may feel uncomfortable answering questions about your pain, mood, or feelings of social connection. You can choose not to answer questions that make you feel uncomfortable.

Loss of Confidentiality
An additional 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.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

Unknown Risks
We have described all the risks we know. If we learn about other risks, we will let you know what they are so that you can decide whether or not you want to continue to be in the study.

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 potential improvements in pain, OUD, and mental health symptoms.

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

You can refuse to participate in the study.

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 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 Investigators in writing at the address on page 1 of this form. However, you may first call or speak to one of the Principal Investigators and they 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?

If you do not attend an in-person art workshop, your participation in the study will end. 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

CONSENT TO PARTICIPATE

Do you have any questions?

Do you voluntarily consent to participate in this research? (Record potential subject's response)
[ ] Yes [ ] No

_____	_____
Printed name of participant	Date