Study Title:

Motivational Interviewing and Guided Opioid Tapering Support to Promote Postoperative Opioid Cessation

NCT03659734

Document Date: 2/26/2019

Electronic Consent

Instructions: Thank you for your interest in the Mood And Perioperative Pain (MAP-Pain) Trial! Thanks to your participation, we can continue to research innovative improvements in post-surgical care, and better understand the relationship between pain, mood, and medication during recovery.

Before enrolling in this research study, it is important for you to read and understand the following consent form. It explains MAP-Pain, your rights and responsibilities as a participant, as well as how your health information will be collected and used. Please make sure you understand this form in full and ask any questions before signing. For questions, please contact Luke Pirrotta, STOP's coordinator, at 650-721-2991 or at lxp@stanford.edu

This is an electronic consent form, meaning that you can sign the form online. There are two questions to answer and two places to sign. Upon completion, please hit the "submit" button, but please note that you may not return to the electronic form after it is completed. Attached below is a paper copy of the consent form that you should download for your records.

Thank you for your participation and we look forward to speaking with you!

- The MAP-Pain Research Team

If you have spoken with a member of the research team about the consent form, you may now answer the questions below.

If you do not wish to participate in this study, please close this form now.

Are you participating in any other research studies?

◯ Yes
◯ No

Download the Full Consent form by clicking the link below

[Attachment: "Observation Consent.pdf"]

Download the full consent form by clicking the link below

[Attachment: "Intervention Consent.pdf"]

Stanford University Research Consent Form
Mood And Peri-operative Pain (MAP-Pain) -- Intervention Trial
IRB Approval Dates: April 17, 2018- April 17, 2019

PURPOSE OF RESEARCH
You are invited to participate in a research study of post-surgical pain and medication use during recovery. We hope to learn more about your pain, mood, and medication use after surgery. You were selected as a possible participant in this study because you are about to undergo surgery.

If you decide to terminate your participation in this study, you should notify Jennifer Hah, MD at (650) 736-9415.

This research study is looking for 558 patients undergoing surgery at Stanford Hospitals and Clinics. Stanford University expects to enroll 400 research study participants. 220 of these patients will be enrolled in the intervention study, and 338 patients will be enrolled in an observational-only study.

VOLUNTARY PARTICIPATION
Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT
This research study is expected to actively enroll participants for 4 years. Each person will continue to participate for as long as they are recovering from surgery and using pain medications. For most people, this will be less than 3 months, but for others participation can be longer. Extended follow-up could last up to 10 years, with the option of stopping follow-up at any time

PROCEDURES
Pre-Surgery
If you choose to participate, Dr. Jennifer Hah and her research study staff will ask you to complete a set of questionnaires before your surgery date, which may take up to 1 hour.

Post-Surgery Follow-up & Intervention
Weekly reports: Each week after your surgery you will be asked to report your experience of pain and your use of pain medications using a web-base questionnaire. If your participation continues for more than 6 months (from your date of surgery), you will be asked to complete the questionnaires on a monthly basis.

Follow-up Questionnaires: After your surgery, you will be asked to complete online questionnaires on a weekly and monthly basis. If your participation continues for more than 6 months (from the date of your surgery), all questionnaires will be completed on a monthly rather than weekly basis.

Prescription Information: In correlation with your daily reports, the research team will also be accessing your prescription information utilizing the California Substance Utilization Review and Evaluation System (CURES) under the California Department of Justice, Prescription Drug Monitoring Program.

Additional Follow-up: We may also contact you up to once every 6 months for 10 years to ask about your pain, medication use, and current medical status. You may choose to stop these follow-up calls at any time.
We will also examine your medical record for variables that may contribute to your pain and recovery, such as information about your surgery, anesthesia, medications, physical exams, or your medical history.

Women of Childbearing Potential
If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

PARTICIPANT RESPONSIBILITIES
As a participant, your responsibilities include:
Follow the instructions of the Protocol Director and study staff.
Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss an appointment
Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
Tell the Protocol Director or research staff if you believe you might be pregnant.
Answer the study questions as instructed.
Complete your questionnaires as instructed.
Ask questions as you think of them.
Tell the Protocol Director or research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the Protocol Directors of each study.

WITHDRAWAL FROM STUDY
If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Jennifer Hah at (650) 736-9415.

The Protocol Director may also withdraw you from the study without your consent for one or more of the following reasons:
Failure to follow the instructions of the Protocol Director and study staff.
The Protocol Director decides that continuing your participation could be harmful to you.
Pregnancy
The study is cancelled.
Other administrative reasons.
Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES
There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

The set of questionnaires that you do before surgery may take up to an hour to complete. The surveys you complete following surgery will only take a few minutes but will need to be completed until you finish the study, a time that averages several weeks but may be longer.

The responses to questions concerning illegal drug use could be harmful to you if they became known outside the study. As explained in the confidentiality statement in this consent, we do not intend to disclose this information. It is possible that, based on information gained from this study, the investigators may be required to report information (e.g., information relating to suicide, physical or sexual abuse) to the appropriate authorities.

There may also be risks which are currently unforeseeable.

POTENTIAL BENEFITS
Patients participating in research studies often have better outcomes even when receiving no clear additional treatment than people who could have participated but choose not to. This is called an "inclusion benefit" and may relate to increased exposure to knowledgeable medical staff.

Another benefit is that what is learned from your participation in this study may lead to a better understanding of post-operative pain, mood, and opioid use; and its management for future patients.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES
The alternative is not to participate. Your standard of care will not be withheld during your participation in this study; your physicians and medical team will continue to provide the normal treatment before and after your surgery.

PARTICIPANT'S RIGHTS
You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

You have the right to refuse to answer particular questions.

CLINICALTRIALS.GOV
A description of this clinical trial will be available on http://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.

CONFIDENTIALITY
The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of evidence of physical or sexual abuse, or the intent to harm yourself or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of the study is to learn more about patients' pain, mood, and medication use following surgery. Your individual health information will be used to learn more about post-surgical recovery, as well as to identify risk factors for continued medication use. Our results and conclusions will be submitted for publication, but no identifying information about you will be published. We may also provide results to our sponsor, the National Institutes of Health (NIH).

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related intervention.

Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Jennifer Hah, MD at 1070 Arastradero Rd, Suite 200, Palo Alto, CA 94304.

What Personal Information Will Be Obtained, Used or Disclosed?

Personal information about you such as your name, date of birth, date of surgery, contact information, and medical record number may be obtained, used, or disclosed in connection with this research study. Your health information related to this study, may also be used or disclosed in connection with this research study, including, but not limited to the information you provide us on your questionnaires and post-surgical assessments, information in your medical record such as your surgical and anesthetic information, medical history, polysomnography and results of oximetry and sleep workup, medication use, physical exams, pain-related information, prescription fill and refill information,, and audio recordings (for quality assurance purposes if undergoing intervention sessions with Dr. Hah).

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

The Protocol Director- Jennifer Hah, MD

The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary

Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

The Office for Human Research Protections in the U.S. Department of Health and Human Services
The National Institutes of Health in the U.S. Department of Health and Human Services
Your treating physician(s) and/or medical care team may receive a notification from our research team informing them you are participating in this research study. This letter and/or correspondence may become part of your medical record.
Audio recordings may be released to an independent rater trained in Motivational Interviewing (MI) outside of the research to assess the MI technique.
Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2090 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

Stanford University Research Consent Form
Mood And Peri-operative Pain (MAP-Pain) -- Observation Trial
IRB Approval Dates: April 17, 2018- April 17, 2019

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There may also be risks which are currently unforeseeable.

POTENTIAL BENEFITS
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Another benefit is that what is learned from your participation in this study may lead to a better understanding of post-operative pain, mood, and opioid use; and its management for future patients.

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ALTERNATIVES
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PARTICIPANT'S RIGHTS
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You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

You have the right to refuse to answer particular questions.

CLINICALTRIALS.GOV
A description of this clinical trial will be available on http://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.

CONFIDENTIALITY
The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of evidence of physical or sexual abuse, or the intent to harm yourself or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

The purpose of the study is to learn more about patients' pain, mood, and medication use following surgery. Your individual health information will be used to learn more about post-surgical recovery, as well as to identify risk factors for continued medication use. Our results and conclusions will be submitted for publication, but no identifying information about you will be published. We may also provide results to our sponsor, the National Institutes of Health (NIH).

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related intervention.

Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Jennifer Hah, MD at 1070 Arastradero Rd, Suite 200, Palo Alto, CA 94304.

What Personal Information Will Be Obtained, Used or Disclosed?

Personal information about you such as your name, date of birth, date of surgery, contact information, and medical record number may be obtained, used, or disclosed in connection with this research study. Your health information related to this study, may also be used or disclosed in connection with this research study, including, but not limited to the information you provide us on your questionnaires and post-surgical assessments, information in your medical record such as your surgical and anesthetic information, medical history, polysomnography and results of oximetry and sleep workup, medication use, physical exams, pain-related information, prescription fill and refill information,, and audio recordings (for quality assurance purposes if undergoing intervention sessions with Dr. Hah).

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

The Protocol Director- Jennifer Hah, MD

The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary

Research Staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

The Office for Human Research Protections in the U.S. Department of Health and Human Services
The National Institutes of Health in the U.S. Department of Health and Human Services
Your treating physician(s) and/or medical care team may receive a notification from our research team informing them you are participating in this research study. This letter and/or correspondence may become part of your medical record.
Audio recordings may be released to an independent rater trained in Motivational Interviewing (MI) outside of the research to assess the MI technique.
Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2090 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

Authorization To Use Your Health Information For Research Purposes:

Information about you and your health is personal and private. It generally cannot be used in this research study without your authorization. By typing your name below, you are authorizing us to use your health information for the purposes of this research study as outlined in the consent form.

Please type your full name.

_____

Study Details

FINANCIAL CONSIDERATIONS
Payment
You will not be paid for your participation.

Costs
If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. You will also be responsible for any co-payments and/or deductibles as required by your insurance. Participation in this study is not a substitute for health insurance

Sponsor
The National Institutes of Health (NIH) is providing financial support and/or material for this study.

COMPENSATION for Research-Related Injury
All forms of medical diagnosis and treatment - whether routine or experimental - involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance.
If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.
You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION
Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Jennifer Hah, MD, (650) 736-9415. You should also contact her at any time if you feel you have been hurt by being a part of this study.

Alternate Contact: If you cannot reach the Protocol Director, please contact the research team at (650) 721-6931.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS
As a research participant you have the following rights. These rights include but are not limited to the participant's right to:
be informed of the nature and purpose of the experiment;
be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
be given a description of any attendant discomforts and risks reasonably to be expected;
be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
be given an opportunity to ask questions concerning the experiment or the procedures involved;
be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
be given a copy of the signed and dated consent form; and
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.

May we contact you about future studies that may be of interest to you?

◯ Yes
◯ No

We may also send you a participant newsletter with updates on this study and other studies in our lab in appreciation of your participation. You may choose to be removed from our contact list at any time.

Consent to Participate:

Typing your name means you agree to be in this study and that you were given a copy of this consent form.

Please type your full name.

_____
(Please make sure you have spoken with the research team before signing)