Partners HealthCare System
Research Consent Form

Subject Identification

General Consent Form Template
Version Date: January 2019

Protocol Title: The Effect of Opioid-Free Anesthesia in TMJ Surgery: A Prospective Study

Principal Investigator: Jinping Wang, MD

Site Principal Investigator:

Description of Subject Population: Surgical Patients

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

Why is this research study being done?

In this research study we want to learn more about the effect of an opioid-free anesthesia strategy in the operating room on postoperative recovery in patients undergoing facial surgery.

How long will you take part in this research study?

If you decide to join this research study, it will take you about three days to complete the study. This includes the day of surgery and two days after. You do no need to return to the hospital for these study visits.

What will happen if you take part in this research study?

If you decide to join this research study, you will be randomized, like the flip of a coin, to either an opioid-free group or to the control group. If you are randomized to the opioid-free group, you will receive all the usual medications for surgery, however we will not give you *additional* opioid medications while in the operating room. When you are transferred to the post-anesthesia recovery area, all usual medications will be resumed, as necessary. It is important to note that even if you are in the opioid free group while in the operating room, you can still receive opioid medications if you experience any discomfort. Additionally this study will include review of your medical record and a phone call two days after your surgery to see what medications you took after surgery and evaluate how you are recovering.

Why might you choose to take part in this study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include reduced postoperative pain or side effects such as nausea or vomiting after surgery. Others undergoing this surgery may benefit in the future from what we learn in this study.

Why might you choose NOT to take part in this study?

Taking part in this research study has some risks and requirements that you should consider carefully. This study will utilize two routinely used strategies for administering medications in the operating room. The risks of the surgery and anesthetic drugs, which are part of your standard care and which you would be receiving whether you participate in the study or not, will be discussed with you separately as part of the clinical consent process. Thus, there is no anticipated risk outside those experienced as part of their routine care. As with any research study there is small possibility of a breach of confidentiality.

A detailed description of side effects, risks, and possible discomforts can be found later in this consent form in the section called “What are the risks and possible discomforts from being in this research study?”

What other treatments or procedures are available for your condition?

You do not have to take part in this study. You can undergo surgery according to the current institutional standards of care without participating in this study.

If you have questions or concerns about this research study, whom can you call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Wang is the person in charge of this research study. You can call him at (617) 643-2729 [M-F 9-5]. You can also call the study team at (617) 726-9252 [M-F 9-5] with questions about this research study.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

Why is this research study being done?

Patients undergoing surgery on their jaw (temporomandibular joint, TMJ) may experience pain after surgery that is often complicated by the opioid medications that are used to treat pain. These complications include the possibility of nausea and vomiting after surgery.

Anesthesiologists routinely employ several strategies to manage the medications they administer while in the operating room, however the optimal strategy is not clear. In this study we aim to evaluate two strategies, namely the use of opioids intraoperatively or not, to evaluate the effect on postoperative recovery after TMJ surgery.

Who will take part in this research?

About 60 people will take part in this research study at Massachusetts General Hospital.

What will happen in this research study?

If you decide to participate in this study the following things will happen:

- **You will be randomly assigned, like the flip of a coin, to one of two common anesthesia strategies**:
    - *Standard Anesthesia Group:* If you are randomized to this group you will undergo surgery according to the current institutional standards of care, which includes the receipt of opioid medications in the operating room.
    - *Opioid-Free Anesthesia Group:* If you are assigned to this group you will receive all the usual anesthetic medications you would normally receive for surgery, however this will not include any opioid medications while in the operating room. In order to manage your care during surgery, you may receive other medications to treat pain that are not considered opioids. These are all medications that you might routinely receive in the operating room.

  Neither you nor the study team will be able to choose which group you are assigned to. Additionally, once you are randomly assigned, only the study team and your surgical team will know which group you were assigned to. We will not tell you which group you were assigned to.

- It is important to know that **regardless of which group you are assigned to, your pain will be treated**. All other aspects of your care and surgery will follow the current institutional standards of care, including preoperative and postoperative medication administration and plans for hospital discharge after surgery.

- Regardless of which group you are assigned to, **we will review your medical record** to collect data on your surgery, the medications you received while in the operating and recovery rooms, your pain after surgery, and other information about your hospital stay.

- **We will ask you a brief questionnaire** about your satisfaction with your pain management when you are leaving the post anesthesia care unit. This survey takes approximately five minutes to complete.

- **We will ask you to complete a medication diary for the first two days after surgery** while you are at home. You will be asked to record all pain medications administered in the first two days after your surgery, as well as information about any pain you are experiencing every 12 hours. This diary will also ask you to record whether or not you experienced any nausea or vomiting after you left the hospital. We will call you after two days to collect this data from you over the phone. After two days your study participation will be considered complete.

Study Information Included in Your Electronic Medical Record
A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of standard blood tests done at the hospital labs).

How may we use and share your samples and health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use these de-identified data in other research. It won't be possible to link the information or samples back to you. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding the effect of intraoperative opioids**.** Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

What are the risks and possible discomforts from being in this research study?

In this study we are evaluating two different anesthetic strategies that are routinely employed as part of the standard of care for TMJ surgery. The risks of the surgery and anesthetic drugs, which are part of your standard care and which you would be receiving whether you participate in the study or not, will be discussed with you separately as part of the clinical consent process. There are therefore no anticipated physical risks associated with this research study outside of what you might experience as part of your routine care. There may be other risks that are currently unknown.

As with any research study, there is a small risk of a breach of confidentiality. Investigators are explicitly trained in the appropriate handling of research data and will be use both physical (locked offices) and electronic (password protected computers) barriers to maintain confidentiality.

What are the possible benefits from being in this research study?

We cannot promise any benefits to you from taking part in this research study. However, possible benefits may include reduced postoperative pain or side effects such as nausea or vomiting after surgery. Others undergoing this surgery may benefit in the future from what we learn in this study.

What other treatments or procedures are available for your condition?

You do not have to take part in this study. You can undergo surgery according to the current institutional standards of care without participating in this study.

Can you still get medical care within Partners if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will not be paid for taking part in this research study.

We may use your information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples or information are used for this purpose.

What will you have to pay for if you take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study
- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)

- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject	Date	Time

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter
As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter	Date	Time

OR

Statement of Other Individual (Non-Interpreter)
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name	Date	Time

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