Version Date: 05.09.2025

CONSENT FOR RESEARCH
The Pennsylvania State University

Title of Project:	Efficacy of low-dose propofol infusion on postoperative nausea and vomiting in patients with prior history of postoperative nausea and vomiting (PONV) or motion sickness.
Principal Investigator:	Revati Kanekar, MD
Address:	Department of Anesthesiology & Perioperative Medicine Penn State Milton S. Hershey Medical Center 500 University Drive Hershey, PA 17033
Telephone Numbers:	Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-4264 After hours call (717) 531-8521. Ask for the anesthesiology doctor on 24-hour call.

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.

Why am I being invited to take part in this research study?

We are asking you to take part in this voluntary research study because it was discovered during the pre-operative anesthesia conversation for your procedure that you have experienced at least one of the following:

1) Motion sickness
2) Nausea and/or vomiting within 24 hours after surgery under general anesthesia

What is the purpose of this research study?

Propofol, is a commonly used anesthetic and can be administered by itself or in combination with other anesthetics such as sevoflurane in patients who have experienced nausea and vomiting after their surgery or who have motion sickness. We currently do not know if propofol used in combination with sevoflurane is better, worse or the same for helping such people in reducing their nausea and vomiting after surgery than using propofol by itself. The purpose of this voluntary research study is to determine which technique is better to decrease nausea and vomiting after surgery in patients who have motion sickness or prior episodes of nausea and vomiting after surgery following general anesthesia.

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How long will the research study last?
Your participation will end after the 24-hour post-surgery phone call by the research team.

What will I need to do?
You will be randomized to receive one of the two techniques of anesthesia mentioned above for surgery. We will ask you to keep track of any symptoms of nausea (urge to vomit), retching (labored, spasmodic, rhythmic contractions of respiratory muscles without expulsion of stomach contents), or vomiting (forceful expulsion of stomach contents) within the immediate 24 hours after surgery. You will be contacted via telephone 24 hours after surgery by a member of the research team who will ask you questions related to nausea or vomiting you may or may not have experienced.

What are the main risks of taking part in the study?
For this study, the main risks to know about are
1)General Anesthesia, Propofol and/ or Sevoflurane: sore throat, Nausea, vomiting, headache, muscle aches. The risk where discussed by your Anesthesia provide for your surgery.
2)Risk of Randomization: You will be randomly assigned to one of the treatment methods which may or may not be effective in decreasing nausea and vomiting for you.
3)Risk of loss of Confidentiality: if your information or your identity is obtained by someone other than the investigators, precautions will be taken to prevent this from happening.

What are the possible benefits to me that may reasonably be expected from being in the research?
We cannot promise any benefits to you from taking part in this study. However, possible benefits include reduced or absent nausea and vomiting after surgery. Additionally, results of this study may benefit other people in the future by helping us find an easy-to-implement, evidence-based, anesthetic technique for preventing nausea and vomiting after surgery in patients who have motion sickness or have experienced nausea and vomiting after surgery in the past.

What happens if I do not want to be in this research?
Participation in the research is completely voluntary. You can decide to participate or not to participate.
You may consider these or other options offered by your anesthesiologist to prevent nausea and vomiting after surgery.

DETAILED INFORMATION
The following is more detailed information about this study in addition to the information listed above.

1. Why is this research study being done?
Propofol is a common and routinely used FDA approved anesthetic. There is some evidence in research studies that it may be helpful in reducing nausea and vomiting after surgery. However, it is not clear what dose is most helpful as it has been beneficial both as sole anesthetic and in low doses. Also, the studies thus far have excluded patients who have experienced nausea and vomiting after surgery or have motion sickness. This research is being done to find out which technique is more helpful in decreasing nausea and vomiting after surgery in patients who have a history of motion sickness or prior history of nausea and vomiting following general anesthesia.
The study plans to enroll 60 participants at Penn State.

2. What will happen in this research study?
- If you decide to take part in the research study, you will be randomly assigned to one of the two groups—Group A or Group B. You have a 50/50 chance of being in either group.
- The Group A participants will receive low dose propofol in combination with sevoflurane during surgery.

- The Group B participants will receive propofol as a sole anesthetic during surgery.
- It is important to know that you will not be told which group you have been assigned to. This is known as blinding—a common technique used in research studies to help minimize the risk of bias and yield more authentic/true results.
- 24 hours after surgery, a member of the research team will contact you via telephone and ask you to report the number of times you experienced nausea (urge to vomit), retching (labored, spasmodic, rhythmic contractions of respiratory muscles without expulsion of stomach contents), or vomiting (forceful expulsion of stomach contents) and any anti-nausea medicine you have taken since your surgery.
- If we are unable to reach you, a second attempt (phone call) will be made 48 hours post-surgery. If still unable to reach you, you will be removed from the study.
- If you are still in the hospital 24 hours after your surgery, you may be called or seen in-person to obtain your nausea and vomiting information.
- In addition, nurses in post-anesthesia care unit (PACU) will collect data while you are in the unit. The nurses with ask you your pain score, record how many times you felt nausea, experienced retching or vomited, and record any anti-nausea medicine you may have received. This is standard post-operative care for all patients.
- Post-surgery review of medical records to see if you experience any allergic reaction to propofol and/or sevoflurane, pain medicine, hypotension and vasopressors received during the surgery. We will collect information regarding your surgery and hospital stay including length of surgery and hospital discharge time
- Once your nausea and vomiting information is obtained, your participation in this research will conclude.

What are my responsibilities if I take part in this research?
If you take part in this research, your major responsibilities will include:

- Providing the research team with the best phone number to reach you at 24 hours after your surgery.
- Recording/keeping track of the number of times you experienced an episode of nausea, retching, or vomiting in the 24 hours after you leave the hospital and the medications taken to prevent or treat it

3. What are the risks and possible discomforts from being in this research study?
The risks are the same as those for general anesthesia, which will be discussed and reviewed with you by your anesthesiologist.
Some of the most common side effects of sevoflurane include:

- Blurred vision, chest pain, tightness or discomfort, choking, dizziness, faintness or lightheadedness, fast, pounding or irregular heartbeat or pulse, low or irregular heartbeat, sweating, spasm of the vocal cords, coughing, agitation and airway obstruction, nausea, vomiting and drowsiness.
- Less common but more serious side effects include malignant hyperthermia (drug induced dangerously high body temperature, rigid muscles or spasms and rapid heart rate), severe allergic reactions, hypersensitivity.

The common side effects of propofol include:

- Hypotension (low blood pressure), hypertension (high blood pressure) or bradycardia (low heart rate), itchy skin, a lightheaded feeling, weak or shallow breathing, burning/stinging at injection site.
- Less common side effects include severe allergic reaction or hypersensitivity.

This is a randomized study and you will be randomly allocated to one of the groups mentioned above which may or may not work to decrease your nausea and vomiting after the surgery. Propofol and propofol with sevoflurane are stand of care options at PSH. One anesthesia regimen may have more or less risks than the other.

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

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

4a. What are the possible benefits to me?

- There is no guarantee that you will benefit from this research. The possible benefits that you may experience from this research study include reduced or absent nausea and vomiting after surgery

4b. What are the possible benefits to others?

- The results of this research may benefit other people in the future by helping us find an easy-to-implement, evidence-based, anesthetic technique for preventing PONV in patients who have a prior history of PONV and/or motion sickness.

5. What other options are available instead of being in this research study?

Participation in research is completely voluntary. You do not have to take part in this study to be treated for your condition. Your anesthesiologist may still choose to administer propofol as a part of your anesthetic or as a sole anesthetic or offer you either or all of the following options to decrease the risk of PONV.

- Preoperative anti-nausea medication (e.g., Emend/aprepitant or scopolamine patch)
- Regional/neuraxial anesthesia
- Minimal use of opioid medications
- Be a part of a different research study, if one is available.

Regardless of your participation in this study, you will receive anti-nausea medications after the surgery as part of the routine postoperative care if you develop nausea/vomiting.

6. How long will I take part in this research study?

If you agree to take part, it will take no more than 1 day (24 hours) of your time to complete this research study. You will be part of this study from the time you sign the research consent form until approximately 24 hours after surgery when you receive a call from the research team. Once the phone call is over, your participation in this study will conclude. In the event we are unable to reach you, we will make another phone call approximately 48 hours after your surgery.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

- Efforts will be made to limit the use and sharing of your personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.
- A list that matches your name with your code number will be kept in a locked file in Dr. Kanakar's office.
- Your research records will be labeled with your code number and your initials, and will be kept in a safe area in the Anesthesia Research Office.

- A copy of this signed consent form will be included in your Penn State Health (PSH) medical record. This means that other PSH healthcare providers will know you are in this study.
- For the purposes of this study, information including your name, medical record number, age, date of birth, gender, phone number, date of surgery, and any reports of PONV will be recorded and kept electronically secure.
- In the event of any publication or presentation resulting from this research, no personally identifiable information will be shared.
- We will do our best to keep your participation in this research study confidential to the extent permitted by law. However, the following people/groups you may check and copy records about this research:
    - The Penn State Institutional Review Board (a committee that reviews and approves human research studies) and the Penn State Human Research Protection Program
    - The investigator, Penn State study staff, and other Penn State professionals who may be evaluating the study or need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
    - People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
    - Organizations that provide independent accreditation and oversight of hospitals and research
    - Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
    - The Office for Human Research Protections in the U. S. Department of Health and Human Services

Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your identifiable information and samples may be shared with that new institution and their oversight offices. Data will be shared securely and under a legal agreement, if applicable, to ensure it continues to be used under the terms of this consent and authorization.

'The research team may use your past, present, and future medical information and records for the purpose of your participation in the research study specifically identified in this authorization. Information that will be disclosed may include information developed as a result of the research study, information that identifies you, and information in your medical record, such as HIV/AIDS diagnosis, drug/alcohol treatment and mental health data. Your authorization will remain in effect until you revoke it. You may change your mind and revoke (take back) this authorization at any time and for any reason. However, any information previously disclosed under this authorization may not be retrieved and may no longer be protected by federal or state privacy laws. To revoke this consent and authorization, contact the Principal Investigator using the information found on the first page of this form. Revocation of, or refusal to sign, this consent and authorization will not impact the care you receive at Penn State that is not related to the research, however, you will be excluded from participation in this research study if you do not provide this consent and authorization

7b. What will happen to my research information and/or samples after the study is completed?

- Your information that is collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

For costs of tests and procedures that are only being done for the research study:

- You or your insurance provider will have to pay for the study agents [propofol and sevoflurane] while you take part in this study. Propofol and sevoflurane are routine anesthesia medications used during surgery.
- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.
- Examples of research-related tests and procedures that may be provided at no cost to you may include: visits to the study site, procedures, research blood draws, and/or questionnaires. Talk to the study team about which items and procedures this includes.

For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment. You should also let any health care provider who treats you know that you are in a research study.

Penn State compensation for injury

- There are no plans for Penn State to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form, you are not giving up any legal right to seek compensation for injury.

9. Will I be paid to take part in this research study?
You will not receive any payment or compensation for being in this research study.

10. Who is paying for this research study?
No funds to support this research are required.

11. What are my rights if I take part in this research study?
Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research, there will be no penalty or loss of benefits to which you are entitled.

The person in charge of this research study can remove you from the study without your permission. Some possible reasons for this are:

- It is discovered that anti-nausea medication was taken within the 24 hours prior to your scheduled surgery
- You disclose a severe reaction/allergy to propofol

During the course of this research, you will be provided with any new information that may affect your health, welfare, or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?
Please call the head of the research study (principal investigator), Dr. Kanakar 717-531-4264 or the anesthesiology doctor on 24-hour call at (717) 531-8521 if you:

- Have questions, complaints, or concerns about the research.
- Believe you may have been harmed by being in the research study.

You may also contact the Penn State Human Research Protection Program (HRPP) at (814) 865-1775 or visit the HRPP website at https://www.research.psu.edu/irb/participants if you:

- Have questions or want information regarding your rights as a person in a research study.
- Have concerns, complaints, or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

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INFORMED CONSENT TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and authorize your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name