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Analyzing the Relationship Between Speed Propofol is Given and Low Blood Pressure

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ADULT RESEARCH SUBJECT INFORMATION AND CONSENT FORM and AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

ANALYZING THE RELATIONSHIP BETWEEN RATE OF INDUCTION AND PERIOPERATIVE HYPOTENSION USING PROPOFOL

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Co-Investigators:	Karen Hovsepyan, MD Andrew Hair, MD Thomas Porter, MD Amanda Verheeck, MD
Study Coordinator:	Kristi Baker BSN, RN
Contact Phone number(s):	(419)-383-3556

Key Study Information:

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Toledo or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all these matters carefully.

The purpose of this study is to evaluate relationship between the rate of propofol injection and blood pressure changes.

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There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include fast or slow heart rate, high or low blood pressure, burning or pain on site of injection, apnea, itching. More detailed information will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by improving anesthesiology practice by choosing more favorable rate of propofol injection.
More information will be provided later in this document.

The time required for your participation is the first hour of the surgery. The rest of the information required to complete the study will be collected by the research team from electronic medical record, without contacting you.

Your participation is voluntary. You can decide not to be in this study or agree to take part now and change your mind later. If you decide to take part in this research or not, or if you decide to take part now but change your mind later, your decision will not affect your routine care.

Alternatives to joining this study is to have an induction with a Propofol rate decided by an Anesthesiologist based on his/her expertise level.

PURPOSE (WHY THIS RESEARCH IS BEING DONE)

You were selected as someone who may want to take part in this study because you are scheduled to have an elective surgery with anesthesia using propofol. The purpose of this study is to evaluate relationship between the rate of propofol injection and blood pressure changes.

DESCRIPTION OF THE RESEARCH PROCEDURES AND DURATION OF YOUR INVOLVEMENT

We plan to enroll 100 participants into this study: 50 in Group A and 50 in Group B. On the day of surgery, you will be randomly split into one of the two groups, like a flip of a coin, 50% chance of being in Group A and 50% chance of being in Group B. Participants in Group A will receive propofol with the rate of 20-40 mg/kg within 10 seconds; this is the standard, approved administration rate by the FDA for propofol anesthesia. Participants in Group B will receive propofol at rate of 20-40 mg/kg in 120 seconds; this slower administration of propofol for anesthesia is not a standard FDA approved rate and is experimental for this study.

Then the research personnel will collect the information such as: weight, age, surgery type, blood pressure, heart rate, oxygen concentration in blood; amount of medication used to support blood pressure or heart rate, opioid medication used to control the pain, amount of administered intravenous fluids. This data will be collected for the first hour after the anesthesia started. Thirty days after the surgery, research personnel will collect information regarding the surgery complications without contacting you.

RISKS AND DISCOMFORTS YOU MAY EXPERIENCE IF YOU TAKE PART IN THIS RESEARCH

- There is a minimal risk of loss of confidentiality,

- Despite Propofol is the most common used drug in Anesthesiology, it has its own side effects, such as:

  - fast or slow heart rate,

- high or low blood pressure,
- injection site reactions (burning, stinging, or pain),
- apnea,
- rash, and.
- itching

RISKS TO UNBORN CHILDREN
On the day of surgery, all childbearing age female are offered to pass a urine pregnancy test. To ensure the safety of the pregnant and the baby, any patient who will be tested positive on pregnancy test or refuse to take a urine pregnancy test, will be excluded from participation in this study.

POSSIBLE BENEFIT TO YOU IF YOU DECIDE TO TAKE PART IN THIS RESEARCH
We cannot and do not guarantee or promise that you will receive any benefits from this research directly.

COST TO YOU FOR TAKING PART IN THIS STUDY
There is no additional cost to you or your insurance regarding the amount of propofol used in this study.

PAYMENT OR OTHER COMPENSATION TO YOU FOR TAKING PART IN THIS RESEARCH
If you decide to take part in this research, you will receive no compensation for the study participation.

ALTERNATIVE(S) TO TAKING PART IN THIS RESEARCH
If you decide not to participate in this study, then propofol administration rate will be decided by an assigned anesthesiologist based on his/her expertise level.

CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION
The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

How will researchers protect my information?
Your research information will be stored in a locked cabinet in the Department of Anesthesiology. Only authorized research team will have access to the information. Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. The identifiable information that is collected from your participation in this research will not be used or distributed for future research.

What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?
Signing this form gives the researchers your permission to obtain, use, and share protected health information about you for this study, and is required for you to take part in the study.

What else should I know about the use and disclosure of my health information?
Participation in research involves using and sharing your health information to conduct the research. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee

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total privacy. By agreeing to take part in this research study, you give to The University of Toledo (UT), the Principal Investigator and all personnel associated with this research study your permission to use or disclose health information that can be identified with you that we obtain in connection with this study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the Institutional Review Board may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study. Your insurance company may ask us for a signed copy of this informed consent form to pre-certify you for the care that is billed to them.
    - If you agree to allow us to provide a signed copy of this form to your insurance company, please place your initials here: ____ (opt-in); if not ____ (opt-out)

- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UTMC medical record.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but the publication would not include any information that would let others know who you are.

We will use this information for the purpose of conducting the research study as described in the research consent/authorization form.

The information that we will use or disclose includes patient's weight, BMI, sex, type of surgery, medication used for induction and during the surgery. We may use this information ourselves, as part of the research study.

Under some circumstances, the Institutional Review Board, or the Research and Sponsored Programs of the University of Toledo or their designees may review your information for compliance audits. If you receive any payments for taking part in this study, your personal information and limited information about this study will be given to The University of Toledo's accounts payable department as necessary to

process payment to you. We may also disclose your protected health information when required by law, such as in response to judicial orders.

The University of Toledo is required by law to protect the privacy of your health information, and to use or disclose the information we obtain about you in connection with this research study only as authorized by you in this form. However, the information we disclose with your permission may no longer be protected by privacy laws. This means your information could be used and re-disclosed by the persons we give it to without your permission.

Your permission for us to use or disclose your protected health information as described in this section is voluntary. However, you will not be allowed to participate in the research study unless you give us your permission to use or disclose your protected health information by signing this document.

You have the right to revoke (cancel) the permission you have given to us to use or disclose your protected health information at any time by giving written notice to Karen Hovsepyan MD, 3000 Arlington Ave, Toledo, Ohio 43614, Department of Anesthesiology. However, a cancellation will not apply if we have acted with your permission, for example, information that already has been used or disclosed prior to the cancellation. Also, a cancellation will not prevent us from continuing to use and disclose information that was obtained prior to the cancellation as necessary to maintain the integrity of the research study.

Except as noted in the above paragraph, your permission for us to use and disclose your protected health information will stop at the end of the research study. If you withdraw your permission, you may no longer be eligible to participate in this study.

A more complete statement of University of Toledo's Privacy Practices is set forth in its Joint Notice of Privacy Practices. If you have not already received this Notice, a member of the research team will provide this to you. If you have any further questions concerning privacy, you may contact the University of Toledo's Privacy Officer at 419-383-6933.

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. You can search this Web site at any time and in order to find information on this trial, you can specifically search for NCT05415436.

What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission, or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Toledo Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the

University of Toledo "Notice of Privacy Practices". This information is also available on the web at https://utmc.utoledo.edu/ut-medical-center/patients/pdfs/privacy_notice_pract.pdf. Note that once your information has been shared with others as described above, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

IN THE EVENT OF A RESEARCH-RELATED INJURY

If you suffer a research-related injury, medical treatment is available, but you can choose where to go for treatment.

The University of Toledo and The University of Toledo Medical Center do not offer reimbursement for medical expenses or other compensation for research-related injuries. In the event that any medical expenses are not reimbursed by the Sponsor, they will be billed to you or your insurance.

By signing this form you do not give up any of your legal rights if you are injured.

In the event of a research-related injury, contact:

Tanaya Sparkle, M.D. Principal Investigator
Assistant Professor Department of Anesthesiology
419-383-4000

VOLUNTARY PARTICIPATION

Taking part in this study is voluntary. You may refuse to participate or discontinue participation at any time without penalty or a loss of benefits to which you are otherwise entitled. If you decide not to participate or to discontinue participation, your decision will not affect your future relations with the University of Toledo or The University of Toledo Medical Center.

NEW FINDINGS

You will be notified of new information that might change your decision to be in this study if any becomes available.

OFFER TO ANSWER QUESTIONS

Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over. If you have questions regarding the research at any time before, during or after the study, you may contact Tanaya Sparkle, MD, or Karen Hovsepyan MD, 3000 Arlington Ave, Toledo Ohio 43614, Department of Anesthesiology, 419-383-3556.

If you have questions beyond those answered by the research team or your rights as a research subject or research-related injuries, please feel free to contact the Chairperson of the University of Toledo Biomedical Institutional Review Board at 419-383-6796.

SIGNATURE SECTION (Please read carefully)

YOU ARE MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THIS RESEARCH STUDY. YOUR SIGNATURE INDICATES THAT YOU HAVE READ THE INFORMATION PROVIDED ABOVE, YOU HAVE HAD ALL YOUR QUESTIONS ANSWERED, AND YOU HAVE DECIDED TO TAKE PART IN THIS RESEARCH.

BY SIGNING THIS DOCUMENT, YOU AUTHORIZE US TO USE OR DISCLOSE YOUR PROTECTED HEALTH INFORMATION AS DESCRIBED IN THIS FORM.

The date you sign this document to enroll in this study, that is, today's date, MUST fall between the dates indicated on the approval stamp affixed to the bottom of each page. These dates indicate that this form is valid when you enroll in the study but do not reflect how long you may participate in the study. Each page of this Consent/Authorization Form is stamped to indicate the form's validity as approved by the UT Biomedical Institutional Review Board (IRB).

Name of Subject (please print)	Signature of Subject or Person Authorized to Consent	Date
Relationship to the Subject (Healthcare Power of Attorney authority or Legal Guardian)		Time a.m. p.m.
Name of Person Obtaining Consent (please print)	Signature of Person Obtaining Consent	Date
Name of Witness to Consent Process (when required by ICH Guidelines) (please print)	Signature of Witness to Consent Process (when required by ICH Guidelines)	Date

YOU WILL BE GIVEN A SIGNED COPY OF THIS FORM TO KEEP.