[redacted]

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: A randomized controlled trial of an intervention to reduce the incidence of hypoxia with nasal CPAP versus standard care during procedural sedation for gastrointestinal endoscopy

Application No. : **IRB 00118466**

Principal Investigator: **Laeben Lester, MD**
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1800 Orleans Street
Baltimore, MD 21287
[redacted]

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.
- 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.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

- During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study physician and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.
- The person being asked to be in this research study may not be able to give consent to be in this study. You are therefore being asked to give permission for this person to be in the study as his/her decision maker.

2. Why is this research being done?

This research is being done to see if a mask that fits over the nose and delivers high flow oxygen (like a sleep apnea mask) is more effective for delivering oxygen and helping you breath than other breathing devices often used during gastroenterology procedures.

All patients routinely have their breathing rate and oxygen levels monitored during surgery and procedures at the Johns Hopkins Hospital. Another goal of this study is to see if we can use different monitors (called the ExSpironTM monitor and SenTec Digital monitor) in combination with our current monitors to detect breathing problems earlier. A third monitor (called a BIS monitor) will be used to measure the level of drowsiness or relaxation from anesthesia.

The ExSpiron^{TM} monitor uses an adhesive (sticky), latex-free, adjustable 5 sensor strip (or padset) which is applied to the chest to measure the amount of air moving in and out of the lung in real time. The ExSpiron^{TM} monitor is approved by the U.S. Food and Drug Administration (FDA) to collect and graphically display lung volumes against time and report the values.

The SenTec Digital monitor is approved by the FDA and uses a heated sensor placed on the skin to measure the level of carbon dioxide (CO_2) in the blood. The study will also help us to understand if a combination of newer devices can help us to better monitor how people breath while undergoing the type of anesthesia used to sedate patients for the kind of procedure(s) you are having today.

The BIS monitor is also approved by the FDA and uses an adhesive (sticky) pad to monitor the level of drowsiness or relaxation from anesthesia medications.

In addition, we will measure concentrations of some natural chemicals that are made in your gut to see if they affect how breathing and blood pressure respond to anesthesia.

People undergoing standard of care monitored anesthesia with sedation for clinically indicated endoscopic gastrointestinal procedures such as colonoscopy, esophagoduodenoscopy (EGD), or combined colonoscopy and EGD or related procedures may join.

How many people will be in this study?

About 240 people are expected to participate in this study.

3. What will happen if you join this study?

You are already scheduled for endoscopic gastrointestinal procedures as part of your standard clinical care.

If you agree to be in this study, we will ask you to do the following things:

Randomization

Before the procedure, you will be randomly assigned (by chance, like flipping a coin) to 1 of 2 groups:

- Participants in Group I will receive oxygen during the procedure through a mask placed over the nose that seals against the face. This mask uses a small amount of pressure, called continuous positive airway pressure (CPAP), which is commonly used to treat obstructive sleep apnea (OSA).
- Participants in Group II will receive oxygen with another device routinely used to deliver oxygen during anesthesia for this type of procedure. The other devices can be a nasal cannula or a non-CPAP facemask, and your anesthesiologist will choose which one to use.

Measurements and Data Collection

As part of your routine care, several monitors including EKG pads will be placed on you. We will collect all of the measurements that are routinely done during procedures with sedation. These routine measurements include your heart rate, breathing rate, blood pressure, and how much oxygen is in your blood.

In addition to these routine monitors, we will attach three additional monitors that will record information for study purposes. The first respiratory monitor will measure your respiratory rate (how many times they breath in a minute), minute ventilation (how much air is moving in and out of the lungs in a minute), and tidal volume (the volume of air inhaled or exhaled in a single breath) using the ExSpironTM monitor study device. To do this, an adhesive (sticky) padset will be placed on the chest. This padset is a latex-free, adjustable strip with 5 sensors similar to the adhesive patches used for EKG's for routine cardiac and respiratory monitoring.

The second monitor will measure the level of carbon dioxide (CO_2) using the SenTec Digital transcutaneous CO_2 monitor to get additional information about your breathing. The transcutaneous CO2 sensor is a small sticker that will be placed on your forehead, cheek, or chest and warmed to a temperature of 42 °C (107 ºF). The sensor will be calibrated and will remain in place for no more than 8 hours. To calibrate the respiratory monitor, you may be asked to breathe through a tube connected to a device called a spirometer for 1-3 minutes while you are in the pre-procedure area.

The third monitor (called BIS) measures the level of drowsiness or relaxation from anesthesia and uses a similar sticky padset with 4 sensors that will be placed on your forehead.

Because we do not yet know how well the study devices work, none of the information from the study device will be given to your doctors or nurses, and it will not be used for your care.

In addition to the routine monitor measurements and the information from the study monitors, we will record any maneuvers or assistance your providers perform to help you breathe during the procedure. These maneuvers are often performed during routine care, and can include adjusting your jaw or chin, changing your position, or changing the way oxygen is delivered to you including breathing for you.

We will collect information about the medications you receive during your procedure.

Lastly, if you agree to be in this study, about 2 teaspoons of blood will be drawn at the time your IV is placed in addition to any blood ordered by your doctors.

Request to collect and store biospecimens for future research
As part of this research study, we would like to ask you to let us store your biospecimens and health information for future research. This research could include other diseases.

The study doctor can provide you with additional information if you have questions. Also, further information about our use of your biospecimens can be found in this consent document under the heading What happens to Data and Biospecimens that are collected in the study?.

Will you allow us to store the biospecimens we collect for this study for use in future research?
YES ☐ _____
Signature of Participant

NO ☐ _____
Signature of Participant

Except for the way oxygen might be delivered to you during your procedure, there will be no change from standard clinical care as part of this study.

How long will you be in the study?
This study will take place during your visit to the endoscopy suite. The study should not significantly impact the length of your visit.

4. What are the risks or discomforts of the study?

Sensors:
You may find wearing the additional adhesive padsets and heated sensor uncomfortable. The heated sensor may be uncomfortable because it is heated to a temperature of 42° C (107° F), but they have been used safely in patients as young as newborns.

CPAP mask:
If you are assigned to Group I with the CPAP mask, you may find it uncomfortable. The mask may leave a temporary red mark in the shape of the mask that will resolve over minutes to hours. With all oxygen delivery devices, your nose and mouth may become dry or you may have a nosebleed. The possibility that this will happen is small. There may be side effects and discomforts that are not yet known.

Confidentiality:
There is the risk that information about you may become known to people outside this study.

5. Are there benefits to being in the study?
There may or may not be a direct benefit to you from being in this study.

If you take part in this study, you may help others in the future.

6. What are your options if you do not want to be in the study?
You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

8. Will you be paid if you join this study?

No.

9. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

10. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

13. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?
Call the principal investigator, Dr. Lester at [redacted]. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?
If you think you are injured or ill because of this study, call Dr. Lester at [redacted] during regular office hours.

d. What happens to Data and Biospecimens that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

14. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form, you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Person Obtaining Consent (Print Name) Date/Time

_____

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time

For ADULTS NOT CAPABLE of GIVING CONSENT (*Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)*

_____

Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law) Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

_____

Signature of Participant, LAR or Parent/Guardian (Print Name) Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

_____

Signature of Physician/Mid-Level Provider (Print Name) Date/Time

_____

Signature of Participant (Print Name) Date/Time

_____

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time
For ADULTS NOT CAPABLE of GIVING CONSENT (*Persons from the following categories in order of priority may be a Legally Authorized Representative: Health Care Agent; Legal Guardian; Spouse; Adult child; Parent; Adult sibling; Friend or other relative)*

_____

Relationship of LAR to Participant (indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law) Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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