Consent Form
Version 10-4-17

Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____

Principal Investigator:	Brooke Corning, MD University of Virginia (UVA) Health System 1215 Lee Street Charlottesville, Virginia 22908 Phone: 434-982-4258
Sponsor:	University of Virginia Department of Gastroenterology and Hepatology

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

This study is being funded by the University of Virginia, Department of Gastroenterology and Hepatology.

Why is this research being done?

Most colonoscopies are performed with the patient lying on their left side. Some doctors, however, perform the procedure with patients on their stomach. Throughout the colonoscopy, however, patients are often re-positioned in a variety of ways; shifted into a prone (on stomach) or supine (on back) position, in order to facilitate passage of the endoscope.

There are a number of patient characteristics that are known to make colonoscopy more technically challenging requiring these positional changes, including a Body Mass Index (BMI) greater than 30. We know that for this group of people, it can be more difficult to move the patient or push on the abdomen to help move the scope (camera). We think that in certain patients, having them lieon their stomach will prove to be a better position because the endoscopy team does not have to move the patient as frequently during the procedure to help the doctor complete the colonoscopy. If the patient does not need to be shifted as much, the hope is that this will cause the colonoscopy to be shorter and more comfortable for the patient.

The purpose of this study is to evaluate whether side or stomach) positioningat the start of a colonoscopy, will result in a more comfortable patient experience as well as a reduced procedure time resulting in decreased need for sedation.

There is no expected difference in the complication rate for either position.

You are being asked to be in this study, because your BMI (body mass index), which is a measure of your body weight for how tall you are, is at least 30 and you are scheduled for a colonoscopy as part of your clinical care.

Up to 150 people will be in this study at UVA.

How long will this study take?

Your participation in this study will require no additional time to the colonoscopy you are already having as part of your clinical care.

Note: You will sign a separate hospital consent that will describe the colonoscopy procedure you are having as part of your clinical care and the risks involved.

What will happen if you are in the study?

SCREENING (will take about 20 minutes to complete):

This will take place the day of your colonoscopy, before the procedure starts.

If you agree to participate, you will sign this consent form before any study related procedures take place. A member of the study team will review your medical history to make sure you are eligible and it is safe for you to participate. If you are eligible, you will proceed with your scheduled colonoscopy procedure.

RANDOMIZATION and STUDY PROCEDURES:

To be done at the time of the colonoscopy.

You will be randomly assigned (like the flip of a coin) to 1 of 2 study groups. You have an equal chance of being assigned to either one of the groups. Neither you nor your doctor can choose which group you are assigned, but you will be told which position you are assigned to.

GROUP 1: Colonoscopy performed with you lyingon your left side.

GROUP 2: Colonoscopy performed with you lying on your stomach.

Before the colonoscopy starts, the study doctor will ask you to lie in the position you have been assigned. If for some reason you cannot stay in this position or your doctor needs to move you, that is OK and should not prevent you from undergoing the colonoscopy. The study doctor will commence with the colonoscopy. After the colonoscopy is over, your participation in the study is complete. No other tests or treatments will be

performed as part of this study. Your participation in the study will not affect any future treatments you receive or any future colonoscopies.

FOLLOW UP:

No further follow-up with you will be required after the colonoscopy. A doctor from the study will look at your medical chart 30 days after the colonoscopy is completed, to see if you had any complications after the procedure. Follo- up health information from our medical chart will be recorded for research purposes.

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.

If you want to know about the results before the study is done:

During the study your study leader will let you know of any test results that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to the position you liein during the procedure: include:

Likely

- Temporary discomfort in the muscles and joints.

Rare but serious

- Trouble breathing causing low oxygen levels during the procedure.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. Possible benefits include: having a faster or more comfortable colonoscopy. In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your illness or condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- Colonoscopy in the position recommended by your doctor

If you are an employee of UVa your job will not be affected if you decide not to participate in this study.
If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will not get any money for being in this study.

Will being in this study cost you any money?

If you participate in this research study, the cost of the colonoscopy procedure will be billed to you or your health insurance provider. You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.
You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include

a) Your study physician is concerned about your health
b) You do not follow your doctor's instructions

How will your personal information be shared?
The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:
- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?
- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

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.

What if you sign the form but then decide you don't want your private information shared?
You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:
- Obtain more information about the study

- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
Brooke Corning, MD
University of Virginia (UVA) Health System
1215 Lee Street
Charlottesville, Virginia 22908 Telephone: Phone: 434-982-4258

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908 Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Consent from Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE