You Are Being Asked to Be in a Research Study
Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 100 people who are being studied, at Emory.

Why is this study being done?
This study is being done to answer the question: Does green draping in the operating room prior to a hysteroscopy result in a decreased operating room time. You are being asked to be in this research study because climate change will affect global health, with a disproportionate effect on women. Our goal is finding ways to minimize single use products.

Do you have to be in the study?
It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?
If you qualify and choose to join the study, you will participate for this visit. You will be randomized to either standardized full draping or a minimal green draping. The full draping historically includes underbuttocks, two leg drapes, blue towels, and a top drape. The green draping will include only an underbuttocks. None of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. It will assist in our efforts to make operating rooms more environmentally friendly.

What are the risks or discomforts you should know about before deciding?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled “What are the possible risks and discomforts?”

Alternatives to Joining This Study
This is an optional study, the alternative is not to participate.

Costs
There will be no extra costs to you for participating in this study. The study does not plan to pay for any items or services that you may receive if you take part in this study.

There is more information in the “Costs” section further below.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

Emory University and Saint Joseph's Hospital
Consent to be a Research Subject / HIPAA Authorization

Title: Comparing operative times in hysteroscopies with full draping vs green draping

IRB #: STUDY00007357

Principal Investigator: [redacted] MD, PhD Gynecology

Introduction
You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:

- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

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 is the purpose of this study?
The purpose of this study is to determine whether green draping in the operating room prior to a hysteroscopy results in decreased operating room time.

What will you be asked to do?
After consenting, you will be randomized (like flipping a coin) to either standard full draping or green draping. Green draping will include only an under buttocks. This is compared to standard full draping which includes an under buttocks, two leg drapes, blue towels, and a top drape. The rest of your surgery will be the same and will not be affected. Your chart will be reviewed two weeks after the procedure to record outcomes and any complications.

Who owns your study data and samples?
If you join this study, you will be donating your data. You will not be paid if data is used to make a new product. If you leave the study, the data that were already collected may still be used for this study.

What are the possible risks and discomforts?
There may be side effects from the study procedures that are not known at this time.

The full draping historically includes underbuttocks, two leg drapes, blue towels, and a top drape. The green draping will include only an underbuttocks. The green draping is the same draping that is done in office hysteroscopies, which have

been shown to not have any increased risk of infection. Aside from draping differences, the same surgical sterile standards will be upheld in each case. The procedure will be carried out per standard of care and will not deviate based off of research group.

There are no anticipated risks of study participation. The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations or tests. The risks associated with inadvertent disclosure of personal health information will be minimized.

Will you benefit from the study?

This study is not designed to benefit you directly. This study is designed to learn more about the use of single use products in the operating room. The study results may be used to help others in the future.

Will you be paid for your time and effort?

You will not be compensated for being in this study.

What are your other options?

If you choose not to join this study, you will have the standard full draping. The study doctor will discuss these with you. You do not have to be in this study to be treated for your condition.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data linked by the study code, with other researchers at Emory, and Saint Joseph's Hospital or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory and Saint Joseph's Hospital. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

Returning Results to Participants/Incidental Findings

There will be no new results that will need to be shared with participants. There will be no incidental findings from the study.

Medical Record

If you have been an Emory and Saint Joseph's Hospital patient before, then you already have an Emory and Saint Joseph's Hospital medical record. If you have never been an Emory and Saint Joseph's Hospital patient, you do not have one. An Emory and Saint Joseph's Hospital medical record will be made for you if an Emory Atlanta and Saint Joseph's Hospital provider or facility gives you any services or procedures for this study
Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Saint Joseph's Hospital medical record you have now or any time during the study.

Emory and Saint Joseph's Hospital may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory medical record and Saint Joseph's Hospital. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

Tests and procedures done at non-Emory and Saint Joseph's Hospital places may not become part of your Emory and Saint Joseph's Hospital medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Costs

There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will get your protected health information (PHI) from health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA). Because the health care entities are covered by HIPAA, we must have your authorization to get your PHI from them. However, once we get your PHI from the health care entities, it changes from PHI to individually identifiable information (IIHI) and is no longer covered by HIPAA. We will put your IIHI in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not covered by HIPAA.

There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or disclosed for this study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:

- To conduct this research study
- To evaluate the safety and effectiveness of the drug, device and/or other intervention being studied and ensure integrity of the data
- To provide study-related treatment
- To conduct healthcare operations
- To ensure compliance with state and federal regulations and provide oversight of the study
- To determine your health, vital status or contact information should you be unreachable during the study
- For the administration and payment of any costs relating to subject injury from the study

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests, including subpoenas or court orders, that require us to disclose your IIHI.

Authorization to Use IIHI is Required to Participate:
By signing this form, you give us permission to use and disclose your IIHI for this research study.

People Who will Use/Disclose Your IIHI:

- The Principal Investigator and the research staff
- The study monitors and contractors including laboratories if applicable
- Institutional Review Boards (people who provide ethical review of research)
- Other Emory offices and persons who watch over the safety, effectiveness and conduct of the research

In certain cases where a researcher moves to a different institution, your IIHI may be disclosed to that new institution and their oversight offices. The IIHI will be disclosed in a secure manner and under a legal agreement signed by both institutions to ensure it continues to be used under the terms of this consent and authorization.

Expiration of Your Authorization
Your HIPAA authorization will expire once no more PHI is needed from your medical records for this study.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at: [redacted]

At that point, we will stop collecting your IIHI. We may use or disclose the IIHI already collected so we can follow the law, protect your safety, make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to the research records for this study because the study does not include treatment that is billed to insurers or government benefit programs. Your information collected for this study may be disclosed to others without your permission. The researchers, and people and companies working on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposed. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

If you have questions about the study procedures, appointments, research-related injuries or bad reactions, or other questions or concerns about the research or your part in it, contact [redacted].

This study has been reviewed by an ethics committee to ensure the protection of research participants. If you have questions about your **rights as a research participant**, or if you have **complaints** about the research or an issue you would rather discuss with someone outside the research team, contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu.

To tell the IRB about your experience as a research participant, fill out the Research Participant Survey at **https://tinyurl.com/ycewgkke.**

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**