CAROLINAS HEALTHCARE SYSTEM
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title:	**Carolinas Healthcare System / A Prospective, Randomized Trial to Compare the Fluid Capture Efficiency of the "Total Capture Drape" versus a Standard Drape for Hysteroscopy: Innovation for Improved Patient Safety and Surgical Care**
Protocol Number:	**04-16-07B**
Principal Investigator: (Study Doctor)	**Paul Marshburn, MD**
Telephone:	**704-355-3149 (24 Hours)**
Address:	**Carolinas HealthCare System** **CMC Women's Institute - Charlotte** **1025 Morehead Medical Drive, Suite 300** **Charlotte, NC 28204**

INTRODUCTION

Dr. Paul Marshburn and his associates are asking you to participate in this research study of the "Total Capture Drape" hysteroscopy drape (TCD) at The CMC (Carolinas Medical Center) Women's Institute and Carolinas HealthCare System (CHS). You are being asked to take part in this study because you are scheduled to have a hysteroscopy to view your uterus. The purpose of this study is to compare the "Total Capture Drape" hysteroscopy drape (TCD) versus the standard drape during patient surgeries to measure the amount of fluid used as part of the procedure. Excessive patient fluid absorption during hysteroscopy can cause complications during and following surgery. Your study doctor will review risks of hysteroscopy with you as part of your pre-surgery visit. You will be one of approximately 100 people involved in this research project at CHS, and your participation will last the duration of your pre-operative visits and post-operative discharge.

The Total Capture Drape has received determination from the FDA to be "substantially equivalent" to standard hysteroscopy drapes.

HOW THE STUDY WORKS

Subjects will be randomized to receive either the standard drape or the total capture drape. Subjects randomized to the study treatment group one will receive the standard drape while the other subjects will be randomized to study treatment group two to receive the total capture drape. There will be 50 subjects enrolled in each study treatment group of the study for a total of 100 subjects

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taking part in this study locally through CHS. If you agree to be in the study, you will be randomized to one of the two study treatments. Being randomized means that you are put in a group by a chance process, like flipping a coin. We are using this method because it is not clear at the present time, which drape is better. Your chance of receiving either drape is equal.

You will undergo hysteroscopy in the standard clinical protocol. The only difference will be the type of drape used to collect excess/spilled fluid used during the procedure. As part of the hysteroscopy procedure, you will be sedated and the drape will be positioned underneath your bottom and then draped over the table. See Figure 1 below for an illustration of the drape placement.

Standard Hysteroscopy Drape

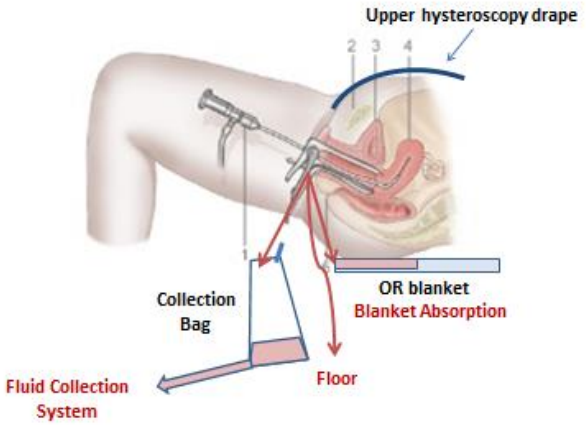

Figure 1.

All women undertaking hysteroscopy are required to have a sterile surgical drape with a fluid capture pouch system to collect the fluid used to distend the uterus that is not absorbed by the patient to calculate the amount of fluid absorbed by the patient. Both the TCD and the standard hysteroscopy drape are used for the purpose of this fluid collection. During your hysteroscopy procedure, we will collect and measure the amount of fluid used in the procedure and the amount captured in the drape (standard or TCD) in order to calculate the amount of fluid that the patient has absorbed. We will compare the amount of fluid that is not able to be measured because it has missed the drape. We will also record the time required for the procedure. Following the hysteroscopy, your study doctor will complete surveys on the effectiveness of fluid capture and usability of each drape.

RISKS

The TCD may not perform in the same manner as the standard drape. The TCD will meet sterilization standards and there is no evidence that the TCD would substantially alter the surgical risks of the hysteroscopy.

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EXCLUSION CRITERIA

You will be excluded from the trial if you are not an acceptable candidate for hysteroscopy for any reason. The exclusion criteria for hysteroscopy are:

- Pregnancy
- Pelvic infection
- Absence of the uterus (womb)
- Severe tightness of the cervix (opening of the womb) that prevents dilation

If you do not wish to participate in the trial you will get the standard care that they normally would have received from your operating surgeon.

BENEFITS

This study may or may not improve your condition. The information gained from your case may benefit others with your condition.

ALTERNATIVE PROCEDURE/TREATMENT

If you choose not to participate in the study, you will receive the standard care that you normally would have received from your operating surgeon.

ADDITIONAL COST

There is no additional cost for participation in this study. You or your insurance carrier will be billed in the usual manner. Your insurance company may not pay for research participation. You may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

COMPENSATION

If complications of hysteroscopy occur during participation in the study, your physician will provide and arrange treatment as necessary, and medical expenses will be billed to your insurance company in the usual manner. You do not waive any legal rights by signing the informed consent form for this study.

WITHDRAWAL

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, it will not in any way harm your relations with your doctors or with Carolinas HealthCare System.

You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Carolinas HealthCare System. If you do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits.

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Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study doctor decides to stop the study.
- The sponsor or the study doctor decides to stop your part in the study for your safety.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.

We will tell you about new medical findings that may affect your willingness to continue in the study.

CONFIDENTIALITY

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed by Carolinas HealthCare System, and/or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

A description of this clinical trial will be available on 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.

AUTHORIZATION

If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study sponsor and the study investigator to collect, process and pass on to the sponsor organizations any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- the clinical study investigator, Dr. Paul Marshburn, and research staff
- the study sponsor and/or its associated companies,
- regulatory or other governmental authorities of the United States and other countries,

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- Carolinas HealthCare System employees,
- other persons or agencies as required by law or allowed by federal regulations.

You have been told that your personal data are being collected and processed to:

- check your suitability to take part in the study,
- monitor your surgery
- compare and pool results with those of other subjects in clinical studies,
- support the development of the study device,
- support the marketing, distribution, sale and use of the TCD anywhere in the world

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Carolinas HealthCare System.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed; it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study investigator and sponsor will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. If you wish to revoke authorization to use your personal information, you will notify the study doctor, Dr. Paul Marshburn, 1540 Garden Terrace Charlotte, NC 28203, in writing. Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

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FINANCIAL DISCLOSURE

Dr. Paul Marshburn, the study doctor, has a proprietary interest in this research study. The study doctor is the inventor of the study device and may benefit financially from future use of this study device. Due to this potential conflict of interest, Dr. Marshbum will not be involved in the informed consent process or recruitment for this study. Speak with the study doctor if you have additional questions.

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Other questions, concerns, or complaints.

Contact the study doctor or study staff at Carolinas Healthcare, listed on the first page of this form, with any questions, concerns or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner. For questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Chesapeake IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please reference the following number when contacting the study subject adviser: Pro00020798.

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STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT

I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent

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