INFORMED CONSENT AND AUTHORIZATION

TITLE: A randomized trial of vaginal preparation solutions to reduce bacteria colony counts in patients having a vaginal surgery.

Investigators: Geoffrey Towers, MD, Rose Maxwell, PhD, James Saelens, MD Wright State University Department of Obstetrics and Gynecology

Sponsor(s) name and address: Wright State University Department of Obstetrics and Gynecology, 128 E. Apple Street, Weber CHE Suite 3800, Dayton, OH 45409

Site where study is to be conducted: Miami Valley Hospital

Phone number for subjects to call for questions: (937)-208-2342

Introduction

The purpose of this consent form is to give you information about this research study. It will describe the purpose, procedures, benefits, risks, and discomforts of this study. The principal investigator and/or the study staff will discuss this study with you and explain everything in detail. Please ask them to explain any words or information that you do not clearly understand.

It is up to you to decide whether or not to take part in this study. If you choose not to participate your decision will not affect your current or future relationship with Wright State University or Premier Health nor will it affect your health care at Premier Health. If you decide to participate, you are free to withdraw at any time without affecting that relationship. Please read this entire consent form and take your time to make your decision. We encourage you to talk to your doctor, your family, and/or your friends before you decide.

Who is conducting and funding this research study?

Wright State University (WSU) will be conducting this trial under the direction of Dr. Towers, principal investigator. This study is being carried out with funds received from the Wright State University Department of Obstetrics and Gynecology.

Why is this research study being done?

The purpose of this study is to compare how well four surgical site preparations work for decreasing bacteria counts in the vagina and whether each preparation can reasonably be expected to reduce post-surgical infection.

Why am I being asked to participate in this research study?

You are being asked to take part in this study because you are scheduled to have a surgery with a vaginal antiseptic preparation.

How many people will be in this study?

Approximately 60 female subjects may be involved in this research at Wright State University.

What will happen if I take part in this research study?

If you agree to be in this study, the following will happen:

BEFORE YOU BEGIN THE STUDY – SCREENING PROCEDURES

Your physician or the research team will review your medical records to find out if you can be in the study. The items they will review include:

- Medical history, including allergies.
- Medications and supplements you are currently taking.

DURING THE STUDY

This research will take place at Miami Valley Hospital.

If you agree to take part in this study, you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance (like pulling numbers out of a hat). A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group (also referred to as an "arm") you will be in. You will have an equal chance of being placed in any group.

If you are in **Arm A** you will have baby shampoo for your surgical preparation. Bacteria counts before cleansing, 10 minutes after cleansing, and after the surgery will be compared with the other 3 Arms.

If you are in **Arm B** you will have betadine for your surgical preparation. Bacteria counts before cleansing, 10 minutes after cleansing, and after the surgery will be compared with the other 3 Arms.

If you are in **Arm C** you will have Techni-Care for your surgical preparation. Bacteria counts before cleansing, 10 minutes after cleansing, and after the surgery will be compared with the other 3 Arms.

If you are in **Arm D** you will have Peridex/chlorhexidine gluconate for your surgical preparation. Bacteria counts before cleansing, 10 minutes after cleansing, and after the surgery will be compared with the other 3 Arms.

How long will I be in this research study?

If you choose to take part, you will be on the study for approximately 1 month after your surgery.

Before your incision is made, the doctor will take a sample using a swab to measure the amount of bacteria at the site where the incision will be made. Then the hospital staff will cleanse the site where the incision will be made using the preparation that you have been assigned. After 10 minutes, the doctor will take a second sample using a swab to measure the amount of bacteria that remains after the cleansing. After your surgery, the doctor will take a third sample using a swab to measure the amount of bacteria that remains after the surgery.

You will have a follow-up phone call 2 days, 2 weeks, and 1 month after your surgery to answer questions about vaginal irritation, itching, and other symptoms during your recovery. This information may be collected during post operation appointments and by phone call.

Can I stop being in this research study?

If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without any penalty. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

The principal investigator or study staff may also withdraw you from the study and the surgical preparation may be stopped, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the research study staff.
- You have an allergic reaction to your assigned surgical preparation.
- You need treatment not allowed in the study.
- The study is cancelled.
- The principal investigator believes it is in your best interest.

What are the potential risks and discomforts from being in this research study?

A risk of this research is a loss of privacy (revealing to others that you are taking part in this study) or confidentiality (revealing information about you to others to whom you have not given permission to see this information).

Risks and side effects for Arm A (baby shampoo):

Less Likely:

- skin irritation

Risks and side effects for Arm B (betadine / iodine):

Likely:

- skin irritation

Less Likely:

- allergic reaction to the iodine in betadine including:
    - severe rash, hives, skin irritation, redness, itching, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
    - Contact your doctor if you have any of these severe side effects.

Risks and side effects for Arm C (Techni-Care):

Likely:

- skin irritation

Less Likely:

- allergic reaction to the ingredients in Techni-Care which may include:
    - severe skin irritation, fever, bleeding or infection.
    - Contact your doctor if you have any of these severe side effects.

Risks and side effects for Arm C (Peridex/ chlorhexidine gluconate):

Likely:

- skin irritation

Less Likely:

- allergic reaction to the ingredients in Peridex, which may include:
    - blistering, burning, itching, peeling, skin rash, redness, swelling, or other signs of irritation on the skin, swelling of the face, hands, or feet, trouble breathing.
    - Contact your doctor if you have any of these severe side effects.

If you have a known allergy to any of these surgical preparations, you should not be in this study.

You may have an unknown allergy to one of the surgical preparations used in the study. If this occurs, you will be treated for the allergy.

Risks and side effects for swab collection:

- minor skin irritation

Unknown:

There may be risks from the surgical preparation that are not known at this time.

Are there benefits to taking part in this research study?

You may not receive any personal benefit from being in the study. The researchers hope that information learned from your participation in this study will increase knowledge about which way is best to treat patients like you. This knowledge will help make it possible to provide the best type of treatment for patients in the future. While you may or may not personally benefit from being in this study, your participation will provide a benefit to others with this condition and to society.

What other options are there?

You have the option to not participate in this study.

What about privacy and confidentiality?

The people who will know that you are a research subject are members of the research study staff, and your physicians and nurses. No information about you, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your rights or welfare or if required by law.

The following groups will have access to study records that identify you:

- Wright State University Institutional Review Board (IRB, including the WSU IRB Office and the Office of Research and Sponsored Programs
- Office of Human Research Protections, under the Department of Health and Human Services

A possible risk of the research is that your participation in the research or information about you and your health might become known to individuals outside of the research team.

Identifiers will be removed from your identifiable private information (or/and identifiable biospecimens). After such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without your consent.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

FDA Clinical Trial Registry

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if I am injured as a result of my participation in the research study?

If you feel that you have been injured as a result of participating in the research, contact the researcher (Dr. Towers) at 937-208-2342 to talk to them about your illness or injury.

There are no plans for Wright State University to provide free medical care or to pay for research-related illnesses or injuries, or to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries.

You or your insurance company will be billed for this medical care. Your insurance company may not pay for some or all of this medical care because you are participating in a research study.

By signing this form you will not give up any legal rights.

What are the costs for participating in this research study?

There are no costs to you for participating in this research. The four surgical preparations are commonly used in gynecology surgery. You and your insurance carrier will be responsible for the costs associated with the regular care for your medical condition. You should check with your insurance company to verify coverage or payments of these procedures.

Laboratory analysis for bacteria colony counts from the swabs will be paid by the Wright State University Department of Obstetrics and Gynecology.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will not be reimbursed for participating in this research study.

Will I be told about new information that may affect my decision to participate in this research study?

During the course of the study, you will be informed of any significant new research information (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the research. If new information is provided to you, you may be asked to sign a consent form that includes the new information.

Who should I contact if I have questions?

Contact the researcher (Dr. Towers) at 937-208-2342 if you have any questions about this study or your part in it or if you have questions, concerns or complaints about the research.

If you have any questions about your rights as a research subject, you may call the Wright State University Institutional Review Board (IRB) at (937) 775-4462. The IRB is an independent committee composed of members of the University community, staff of the institutions, as well as lay members of the community not connected with these institutions. The IRB has reviewed this study.

What are my rights/responsibilities as a research subject?

As a subject, your responsibilities include:

- Follow the instructions of the research study staff.
- Keep your study telephone appointments. If it is necessary to miss an appointment, please contact the research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Ask questions as you think of them.
- Tell the research staff if you change your mind about staying in the study.

While participating in this research study, you should not take part in any other research project without approval from the research staff of each study.

Authorization to Use and Disclose Your Health Information

State and Federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect the privacy of your health information. This section of the consent form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information (PHI) for this research study. Please read this section of the consent form carefully.

If you sign this document, you give permission to (Dr. Towers) and his Wright State/Premier Health research team to use or disclose (release) the following protected health information:

- Your medical records for past medical conditions, including allergies, and medications related to your health
- All information (research records and medical records) created during your participation in this research study
- All information related to illness or hospitalizations that occur during your participation in this study

The research team needs this information to conduct the study. This is a study to test how well the four surgical preparations work for reducing bacteria colony counts before surgery in order to prevent infection after surgery.

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally would have access to your health information.

Disclosure of your protected health information

If you sign this form, the researchers may share your health information during the conduct of the study with:

- WSU's Institutional Review Board (or other IRB of record), which oversees our research
- Representatives of government agencies in the United States and other countries (i.e. Food and Drug Administration and the Office of Human Research Protection)
- Other authorized WSU/PH Officials who oversee research and clinical care

The people listed above will use and share your health information to review the quality, safety, and results of the research and may also do additional research.

Please understand that these persons/organizations who may receive your health information may not be required by U.S. Federal privacy laws (such as HIPAA) to protect it and may share your information with others without your permission.

This authorization does not have an expiration date.

However, you can change your mind and cancel this authorization at any time. To cancel this authorization, you must write the study investigator listed at the beginning of this consent form.

If you cancel this authorization, you will no longer be allowed to take part in the research study. If you cancel this authorization, health information you had already allowed us to obtain may still be used and disclosed by researchers in order to maintain the integrity

and reliability of the research, and to report any adverse (bad) effects that may have happened to you.

Right to refuse to sign this Authorization

You have the right to refuse to sign and give your authorization. If you do not sign this form, your non-research related treatment, payment or enrollment in any health plans, or your eligibility for other medical benefits at Premier Health will not be affected in any way.

However, if you do not sign this form, you will not be able to participate in this research study.

Signature of Subject

I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research and authorize the use and disclosure of my protected health information for this study. I will be given a copy of this signed and dated form.

_____ _____

Signature Date

_____

Printed Name

_____

Signature of Person Obtaining Consent and Authorization

_____

Date

_____

Printed Name of Person Obtaining Consent and Authorization