UPMC Magee-Womens Hospital
300 Halket Street Pittsburgh, PA 15213-3180

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

STUDY TITLE: FAME103B: A Randomized Double-Blind Cross-Over Trial of Self-Insertion of Two Formulations of a Placebo Vaginal Film

INFORMED CONSENT VERSION: Version 2.0, 01Jul2020

PRINCIPAL INVESTIGATOR: Katherine Bunge, MD
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QUESTIONS ABOUT THE STUDY: Contact the research staff at 412-641-4242

FUNDING AGENCY: National Institutes of Health; ClincalTrials.gov ID: NCT04391036
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YOUR PARTICIPATION IS VOLUNTARY
You are being asked to take part in a research study. Research studies include only people who choose to take part. The study team will explain the study and will answer any questions. You should take your time to make your decision and discuss with others if needed.

PURPOSE OF THE STUDY AND STUDY PROCEDURES
The purpose of this study is to determine if women can self insert two different vaginal films. The films differ by level of binding agent (high level and low level). They are small, (~2 by 2 inches), thinner than paper, and are inserted with a finger. The films being used in this study are placebo (blank, no medication) films.

These films may be used in future studies of HIV prevention. This study is only to determine how successful women are at inserting each film and which film they prefer. We will recruit 30 healthy, non-pregnant women between the ages of 18 – 45 who agree to self-insert two placebo films. Ensuring that the vaginal film is placed appropriately and consistently is important for future studies.

The study involves a single visit less than an hour in length, conducted in the UPMC Magee Womens Hospital Clinical and Translational Research Center (CTRC) and includes the following:

- A brief questionnaire including the collection of demographics and previous film use
- Collection of your height and weight
- A urine pregnancy test. If you are pregnant, you will not be eligible.
    - An HIV test, which screens for antibodies to HIV (Human Immunodeficiency Virus). Those infected with HIV may develop AIDS (Acquired Immunodeficiency Syndrome). HIV can be passed to others by intimate sexual contact, sharing needles, body fluid donation, or childbirth. It is important that you know the potential risks and benefits before the HIV test is performed. The HIV test for this study will be done through saliva testing. You will be given a special paddle (an absorbent material on a stick) and instructions on how to collect a sample from your gums and inner cheek. Thetest

takes 20 minutes to run once the sample is obtained. You will be given the result before the end of the visit.
  - A positive HIV test means that the sample tested positive for antibodies to HIV. Repeat tests would be needed to confirm this finding. If the sample is positive for antibodies to HIV, it means that the person has been exposed to HIV and is a carrier of HIV. It means that the virus can be passed to others by intimate sexual contact, sharing needles, body fluid, or childbirth.
  - A negative HIV test means that at this time, no antibody to HIV was found in sample based on the result of the initial screening test.
  - There can be individuals who have HIV test results that are called "false positive," (for some reason the test shows that HIV antibodies are present in the blood/saliva when they are not).
  - There can be false negative results which can have two possible meanings: 1) The person has been infected with HIV, but the body has not yet made antibodies to the virus; or 2) HIV antibody is present in the person's blood/saliva, but for some reason the test failed to detect it.
  - If your rapid test is positive, you may either be asked to give approximately 4 mL of blood or may be referred to the local health department for confirmatory testing. You will be counseled on the risks for transmitting HIV and developing AIDS as well as available treatments and services.
- Two vaginal swabs will be collected for sexually transmitted disease testing (chlamydia, gonorrhea and trichomonas). You will only be notified within a week of your visit if your test result is positive and you require treatment.
- You will be randomized (like flipping a coin) to the order of insertion of the two different films (low binding agent and high binding agent). You will be given instructions on how to insert them. Neither you or the study clinician or staff will know which film order you have been randomized to. You are not able to choose which order of film to use.
- After inserting the first film, the clinician will insert a speculum to determine location and appearance of film.
- With the speculum still in place, the visible film will be removed.
- You will be asked to answer some questions about the first film.
- The same process will be repeated for the second film.
- After attempting to insert both films, additional questions will be asked about preference of film and comparisons between the two films.
- Participation in the study will end.

RISKS AND/OR DISCOMFORTS

The risks of participating in this study are minimal and include the following:

Procedure	Risk
Pregnancy Test, STD/HIV test	• Anxiety surrounding the test or waiting for results • Denial, depression or worry with unexpected positive result
Pelvic Exam	• Discomfort with speculum
Placebo Film	• Discomfort with insertion • In previous studies using vaginal film, women reported vaginal itching and bacterial vaginosis
Participation in research	• Inconvenient • Breach of confidentiality
Blood Draw for	• bruising, soreness, pain/discomfort, bleeding, infection at the site lightheadedness, fainting

confirmatory HIV testing, if needed	

You will be notified of any results that might affect your personal health or decisions. In the unlikely event that a clinically significant, unexpected disease or condition is identified while you are participating in this study, you would receive applicable referral for care.

BENEFITS
You will get no benefit from participating in this study.

NEW INFORMATION
You will be told of any new information learned during this study that might affect your willingness to stay in the study.

BEING WITHDRAWN EARLY
Since this is a single visit study, it is very unlikely that we would need to remove you from the study early without your permission unless the study was stopped/cancelled. In the event that you are withdrawn/withdraw early, any data collected up until the point of withdraw may continue to be utilized for the study.

COSTS TO YOU
There is no cost to you or your insurance for study visits, the vaginal film, or other study procedures.

REIMBURSEMENT
You will receive $40 compensation for your time, effort, and travel at the end of the study visit. Payments will be made on a reloadable debit card. The cost of treatment for any infection identified through the study (STDs/HIV) will not be covered through the study.

Payment received as compensation for participation in research is considered taxable income for a research subject. If payments are more than $600 in any one calendar year, University of Pittsburgh is required to report this information to the Internal Revenue Service (IRS). Research subject payments exceeding $600 during any calendar year will result in a 1099 (Miscellaneous Income) form being issued to the research subject and a copy will be sent to the IRS.

CONFIDENTIALITY
Every effort will be made to keep your information confidential. We will do that by keeping any paper records in locked files in locked offices and limiting access to only the study team. Study data stored on-line will be de-identified meaning your name or any identifier will be removed and stored only with a study ID. The log that links your name to the ID will be password protected and the PI will control access to it. However, it is not possible to guarantee confidentiality. Your records may be reviewed by the University of Pittsburgh Research Conduct and Compliance Office to be sure the study is being done properly. The data collected as part of this study may be shared and analyzed by the sponsor, NIH and by investigators outside of Magee, including investigators from Carnegie Mellon University.

In addition to the investigators listed on the first page of this consent form and the research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

- Authorized representatives of the NIH and the University of Pittsburgh Office of Research Protections may review your identifiable research information (which may include your identifiable medical record information) for the purposes of monitoring the appropriate conduct of this research study.
- In unusual cases, the investigators may be required to release your identifiable research information (which may include your identifiable medical record information) in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform appropriate agencies, as required by Pennsylvania law.
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to your identifiable information (which may include your identifiable medical record information) for the purposes of (1) fulfilling orders, made by the investigators, for hospital and health care services (such as laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and (3) for internal hospital operations (i.e. quality assurance).

Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of a project. The investigators may use or disclose, for purposes described above, identifiable information (which may include identifiable medical information) related to your being in this study a minimum of 7 years and for as long (indefinite) as it may take to complete this study.

A description of this clinical trial will be available on http://clinicaltrials.gov, as required by US 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state or local civil, criminal, administrative, legislative, or other action, suit or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases) but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings; if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

IF YOU BELIEVE THAT YOU HAVE BEEN INJURED

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow up care. At this time, there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form.

YOUR RIGHTS AS A RESEARCH PARTICIPANT/VOLUNTEER

Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. If you choose not to participate or to leave the study, you will not lose the benefit of services to which you would otherwise be entitled at this clinic.

Your routine care provider may also be a research investigator for this study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under obligation to participate in any research study offered by your doctor.

PROBLEMS OR QUESTIONS

If you ever have any questions about the study, or if you have a research-related injury, you should contact Katherine Bunge, MD or the research staff at (412) 641-4242. If you ever have any questions about your rights as a research participant, you can contact the University of Pittsburgh IRB at 1-866-212-2668.

VOLUNTARY CONSENT

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified member of the research team or by the principal investigator listed on the first page. I understand that I may always request that my questions, concerns or complaints be addressed by the Principal Investigator. At any time, I may also contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable. By signing this form, I agree to participate in this research study for the purposes described above. A copy of this consent form will be offered to me.

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Printed Name of Participant

		AM / PM
_____	_____	_____
Participant Signature	Date	Time

CERTIFICATION OF INFORMED CONSENT: I certify that I have explained the nature and purpose of this research to the above individual and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date