Safety and Pharmacokinetics of Two Vaginal Film Formulations Containing the Integrase Inhibitor MK-2048 (FAME103)

NCT04319718

Document/IRB Approval Date: December 14, 2021

MAGEE-WOMENS RESEARCH INSTITUTE

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

STUDY TITLE: A Randomized, Double Blinded Study of the Safety and Pharmacokinetics of Two Vaginal Film Formulations Containing the Integrase Inhibitor MK2048: FAME 103

INFORMED CONSENT VERSION: Version 4.0, 30Nov2021

PRINCIPAL INVESTIGATOR: Katherine Bunge, MD

Safety and Pharmacokinetics of Two Vaginal Film Formulations Containing the Integrase Inhibitor MK-2048 (FAME103)

UPMC

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Magee-Womens Hospital, Dept of OB/GYN/RS,
300 Halket Street, PGH, PA 15213

QUESTIONS ABOUT THE STUDY: Contact the research staff at 412-641-4242 or after hours at 412-463-1337

FUNDING AGENCY: Division of AIDS, US National Institute of Allergy and Infectious Diseases, US National Institutes of Health

KEY INFORMATION

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 members will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

Summary of study. This study includes approximately 36 healthy non-pregnant women aged 18 – 45 who agree to use a single investigational (experimental) vaginal film and return for 6 follow up visits. The vaginal film, which is a thin square similar to a Listerine® breath strip, contains an investigational medication called MK2048. MK2048 is not approved by the Food and Drug Administration (FDA). This study will assess the safety and acceptability of the film.

Visits (8 in total)	Time	Key component(s) of visit
Screen	Today	Determine eligibility; includes STD/HIV testing
Enrollment	Within 45 days	Vaginal film insertion by a clinician
Required Follow-up Visits	Days 3, 5, 7, 10, 14, 28	Blood and genital* sample collection at each visit; Cervical biopsies and rectal swabs at Day 7 visit only

*Genital samples refer to vaginal, cervical and/or rectal samples

Risks. The main risks of participation include the risks of using an investigational vaginal film, blood draws and cervical biopsies. The number of study visits may be inconvenient.

Benefits. There is no direct benefit to participating, however some participants may get satisfaction taking part in a study that involves women's health.

Right to withdrawal. You may withdraw from the study at any time if you chose.

Alternatives. The alternative is not to participate in this study.
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YOUR PARTICIPATION IS VOLUNTARY

Participation in research is a personal decision; you are under no obligation to participate. If you agree to take part, you will be asked to sign your name on this form and will be offered a copy to keep. Your regular doctor may be part of this study team. You should take your time to make a decision and discuss with others if needed.

STUDY PRODUCTS AND PURPOSE OF STUDY

Two different vaginal films will be tested in this study. Both films contain the same amount of an investigational medication called MK2048. MK2048 has been used in other studies to look at HIV prevention. The two films differ in the amount of polymer ("binding" or "delivery" agent).

Films	MK2048 dose	Size	# of participants
high polymer*	30mg	2" x 2"	24
low polymer	30mg	2" x 2"	24

*used in a previous placebo (blank, no drug) film study of 64 women and was safe and acceptable

The Food and Drug Administration (FDA) has not approved MK2048 film for use. While MK2048 has been tested in humans, including vaginal dosing via vaginal ring, this is the first time MK2048 has been tested in a film form in humans. Importantly, all the ingredients that make up the film, including the polymers have been tested in humans and have been found to be safe.

This study is testing the safety of MK2048 film when used once. Cervical biopsies, vaginal and rectal samples, and blood will be collected to see how much MK2048 gets into the genital tissue and/or bloodstream. The cervical tissue will be exposed to HIV in the lab to understand whether the film can help to prevent HIV infection when tested outside the body.

This study is not testing if MK2048 vaginal film prevents you from getting infected with HIV. Researchers do not yet know if the film will work in humans to protect against HIV. The best way to protect against getting HIV infection during sex is to use a condom every time you have sex.

The first 25 women enrolled were randomized (50/50 chance, like flipping a coin) at visit 2 (V2) to have one of two films inserted (high polymer or low polymer). Due to intolerability issues with one of the film formulations, the remaining 11 participants will all receive the alternate film formulation. Although all remaining participants will receive the same formulation, the study remains blinded and neither the participants nor the study team will know which formulation they are receiving. All women will follow the same study visit schedule.

STUDY VISIT HIGHLIGHTS

- All research activities will take place at UPMC Magee-Womens Hospital.
- All study procedures will be conducted by a member of the ID research team. All counseling and examinations will be conducted by a clinical member of the ID research team that includes mid-level practitioners (CRNP, PA-C) and/or trained study physicians

- A screening visit (V1) will determine if you are eligible to participate. You are under no obligation to participate even if you are found to be eligible. Screening can occur over more than one visit, if necessary.
- If eligible and interested, you will be asked to return within 45 days to be enrolled (V2). At V2, you will have the assigned vaginal film inserted into the vagina by a research clinician.

- There are 6 follow-up visits (V3 – V8). Window periods for visits will allow some flexibility in scheduling study visits. Genital and blood samples are collected to establish your baseline and to check drug levels throughout the study.

	STUDY VISIT							
	SCREEN	ENROLL	FOLLOW-UP					
STUDY PROCEDURES	V1	V2	V3	V4	V5	V6	V7	V8
Day	-45	0	3	5	7	10	14	28
Length of Visit	1hr	1hr	30m	30m	30m	30m	30m	30m
Medical History & Medication review	x	x	x	x	x	x	x	x
Visit Questionnaire	x	x	x	x	x	x	x	x
Collect/update contact information	x	x	x	x	x	x	x	x
HIV Rapid Test	x							
HIV Confirmatory Test	^							
Review Applicable Test Results	x	x						
Protocol Counseling	x	x	x	x	x	x	x	
Urine pregnancy test	x	x			x			x
Urine dipstick test	^	^	^	^	^	^	^	^
Blood draw (MK2048 level)		x	x	x	x	x	x	x
Blood draw (CBC, AST, ALT, Creatinine)	X**						X**	
Pelvic Exam with speculum	x	x	x	x	x	x	x	x
Genital sample collection	x	x	x	x	x	x	x	x
STD testing	x							
Pap smear	^							

CVL (vaginal "wash" with saline)	x						x	x
Cervical Biopsies					x			
Rectal Swab (MK2048 level)					x			
Brief Physical Exam	x	^	^	^	^	^	^	^
Height and Weight	x							
Blood pressure	x	x	x	x	x	x	x	x
MK2048 Film Insertion (by clinician)		x						
Acceptability Questionnaire		x			x			
Compensation	$30	$40	$30	$30	$100	$30	$30	$40
Incentive if all visits in window								$40
Optional procedures		*						

This table outlines the visit schedule and study procedures.
^ as necessary
* V2 INCLUDES OPTIONAL SAMPLING: You may choose to have up to two vaginal swabs collected without a speculum and one blood sample collected following film insertion. ○ Optional collection times are at 1, 2, 3, 4, 5, or 6 hours following film insertion.

- ○ Additional compensation will be provided for each sample collected as follows:

	1, 2, 3 hour collection	4, 5, 6 hour collection
Vaginal Swab	$10	$20
Blood Sample	$20	$30

**Screening labs may be re-drawn within the screening window period (45 days) if there is a laboratory issue (i.e. not enough blood was drawn, lab error, etc.) or for a test result that is out of range for enrollment. Blood collected at V7 may also be redrawn as necessary for laboratory issues and/or out of range results.

ADDITIONAL STUDY VISIT PROCEDURE INFORMATION

- Visit Questionnaires include asking things like sexual history, vaginal product use, and vaginal symptoms
- HIV testing will be done as part of the study.
  - ○ A saliva sample will be tested for the antibody to HIV. An antibody is a substance that blood cells make to fight infection. Exposure (contact) to the HIV virus produces antibodies. ○ Results take 20 minutes. Study staff will talk to you about the meaning of the result, how you feel, and ways to prevent HIV and other sexually transmitted infections.
  - ○ Sometimes HIV test results are not clearly positive, but also not clearly negative. In that case, blood will need drawn and sent to the lab for further testing which could take

a week. ○ If the test shows you have HIV, you cannot join the study. You will be referred for medical care and other services. Your partner(s) may have access to free HIV counseling and testing, if needed.

- You will only get the results of tests that are applicable to your clinical care, including pregnancy test, STD and HIV tests, and evaluation for vaginal complaints if performed. You will not get the results of the other tests as they are done for research purposes only.
- Protocol counseling includes visit reminders, STD/HIV and abstinence counseling, and vaginal product use. ○ You must agree to not have sex (vaginal, anal and receptive oral) from V2 – V7 (about 14 days).
    - You must also agree to not have sex 48 hours before the other study visits.
    - You must agree not to use vaginal products during the study and no tampon use between V5 – V7 (about 7 days).
- Blood will be drawn to test MK2048 levels. Approximately 2 teaspoons of blood will be drawn each time.
- Blood will also be drawn at the screening visit (V1) and the end of treatment visit (V7) to test the health of your blood as well as liver and kidney functions. Approximately 2 teaspoons will be drawn for these tests. If there is a problem with the blood sample collected (i.e. not enough blood was drawn for the test, a lab error, an out of range result, etc.) you may return during the 45 day screening window to have the blood test performed again to see if you are eligible for enrollment. If the problem occurred with the V7 blood draw, you may be asked to return to the clinic or have your blood re-drawn at V8. You may be referred to your primary care physician for follow up in the event of a significant clinical finding.

- Genital sample collection includes collecting Q-tip like swabs from the vagina, cervix and rectum. The samples will be used to look at bacteria and other markers.
- STD (sexually transmitted disease) testing will include Chlamydia, Gonorrhea and Trichomonas.
- CVL (cervicovaginal lavage) is a vaginal “wash” of the vagina with saline; the wash takes one minute.
- Cervical biopsies will be collected by a qualified, licensed investigator (i.e MD, DNP) at V5 (Day 7).
    - Two adequate samples will be collected, approximately 3mm each or the size of a grain of rice.
    - The biopsy sites take approximately 7 days to heal. As a reminder, do not put anything in the vagina (tampon, sex toy) and avoid any type of sex (vaginal, anal, receptive oral) for 7 days.
- Study procedures can be repeated as needed (e.g. collection or processing error, or for clinical reasons).
- Microscopic exam (looking under a microscope) of vaginal discharge, urine dipstick and bimanual exam (to feel uterus and ovaries) may be done as clinically indicated during the study.
- Interim or unscheduled visits may occur if needed (e.g. abnormal results, repeat testing, side effects).
- Study participation for the required visits end at Visit 8 (Day 28).
- If you have ongoing side effects at V8, study staff may call you until the issue stabilizes or resolves.

- In the unlikely event you become pregnant while participating in the study, the study staff will refer you for appropriate care. You will be exited from the study, but study will need to follow up with you by telephone until the outcome of your pregnancy is known.
- If you are found to have an Gonorrhea, Chlamydia or Trichomonas or a vaginal infection during the study, you may be provided with directly observed antibiotic treatment.
- The samples for this research study will be sent to Magee-Womens Research Institute (MWRI) where most of the samples will be processed. Some samples may be sent to outside investigators for processing or analysis. Importantly and regardless of lab, all samples are sent with a unique study number. No personal identifiers (name, SSN, birthdate) will be on the samples.

RISKS AND/OR DISCOMFORTS

By participating in this study, you could have these side effects or other side effects that we do not know about.

Procedure	Risk
Pregnancy Test	• Anxious or nervous having test or waiting for results • Denial, depression or worry with unexpected positive result
Pelvic Exam	Discomfort with speculum
Genital and rectal specimens	Minimal discomfort from collection of specimens
Cervical Biopsy	• Generally well tolerated but may cause pain (or pinching) • Cramping similar to menstrual cramps ○ Cramping typically resolves within minutes after procedure ○ May take ibuprofen prior to biopsy to minimize cramping (risks of ibuprofen may include nausea, upset stomach and rash) • Vaginal spotting or bleeding for a couple days
	○ Typically less than a period but if heavier, contact study staff Infection of biopsy area ○ Unlikely but if foul odor or unusual discharge, contact study staff A cut in the vagina can put you at increased risk of getting HIV if exposed If you have an IUD, there is a risk of dislodging it with performing the biopsies. If displaced, a new IUD will be inserted at no cost to you
Vaginal use of MK 2048 film	Vaginal discharge, irritation, discomfort Vaginal burning, itching, redness and/or pain; Yeast or vaginal infection Allergic reaction
Blood draw	Bruising, soreness, pain/discomfort, bleeding, infection at the site lightheadedness, fainting

Participation in research; collection and storage of private health information, biospecimens and internet communication*	☐ Inconvenient ☐ Breach of confidentiality
Questionnaires	☐ Discomfort with personal nature of questions
STD/HIV testing	☐ Worry or anxiety ☐ Sadness, depression or denial with a positive test result ○ Positive gonorrhea and chlamydia test results will be reported to ACHD according to the Commonwealth of Pennsylvania reporting requirements ○ May be contacted and asked questions about sexual partners

*We will make reasonable efforts to protect the privacy of information on social media. Each platform has their own privacy policies and terms of use that may change at any time. The University of Pittsburgh cannot guarantee the privacy and confidentiality of information shared on social media in this research study. Your information may not remain private. You will be instructed to visit site privacy policies and update privacy settings, as necessary. Social media retains information shared across accounts for an unknown length of time and it may be shared with others including targeted advertisers.

Pregnancy, Breastfeeding and Sexual Practices

The vaginal film is not a birth control method. We do not know what effect the study drug may have on pregnancy, including the effect of the study drug on the fetuses of women who use the vaginal film when pregnant, or the babies of women who use the vaginal film when breastfeeding. Because of this, pregnant women and women who are breastfeeding may not join this study. Women who join the study must agree to avoid sexual intercourse from V2 (enrollment) until V7 (7 days after the biopsy visit), and 48 hours prior to each study visit, use an effective method of birth control and have scheduled pregnancy tests while in the study. Effective methods of birth control include hormonal methods (like "the pill" or Depo-Provera injections), the IUD, sterilization (or "tied tubes"), abstinence (or not having sex), same sex partner, or having a partner who has had a vasectomy. You must agree to use this method of birth control until the last study visit, approximately 4 weeks after you are enrolled.

If you do not think you can be sexually abstinent until at least 7 days after the biopsy visit, then you should not enroll in this study. In the unlikely event that you become pregnant during the study, study staff will refer you to available medical care and other services you or your baby may need. The study does not pay for this care. You will keep coming here for study visits as originally planned. We will change the study procedures as needed to protect your health while you are pregnant. The outcome of your pregnancy is important to study staff; you will be followed through the outcome of your pregnancy.

If you were to become HIV infected while using the study product, the HIV virus may develop resistance to MK2048. Developing MK2048 resistance means that the MK2048 may not be able to treat HIV however, MK2048 is not currently used to treat HIV.

BENEFITS

You will not directly benefit from participating in this study. You may, however, feel satisfaction knowing that information learned from this study may help in the development of vaginal products for women. You will also have exams and HIV/STD testing as part of your participation in this study.

NEW INFORMATION

You will be told about any new information learned that might affect your willingness to stay in the study.

CLINICALLY RELAVENT RESEARCH RESULTS: You will be given the results of your pregnancy, STD and HIV testing. Counseling, referrals and treatment will be discussed as applicable. There is no plan to provide you with your results for tests collected for research purposes only or results of the study in general once it is completed.

STOPPING STUDY DRUG OR BEING WITHDRAWN EARLY

The study staff may remove you from the study early without your permission if:

- The study is stopped or cancelled
- You are not able to keep appointments
- Other reasons that may prevent you from completing the study successfully or safely. This would include a newly diagnosed pregnancy or HIV. If you become pregnant, although you will be terminated from further study visits, study staff will continue to contact you through the outcome of your pregnancy.

Participants who withdraw or who are withdrawn from the study prior to completing follow up may be asked to complete a final study visit.

COSTS TO YOU

There is no cost to you or your insurance for study related visits or procedures.

REIMBURSEMENT

You will receive compensation for your time, effort, and travel expenses as detailed in the study procedure table above. If you complete all the required study visits within the designated window periods, you will receive a total of $370. If you complete all the required study visits and the optional V2 procedures, it is possible to be compensated up to $440. If you complete a visit but are seen outside of the protocol window for that visit, $10 will be deducted from the scheduled visit payment.

Parking passes or assistance with transportation will be provided as needed.

Since you are being compensated for participation in this study, your name, address, and social security number will be released to the Accounting Office. If the total reimbursement for your participation in research is greater than $600 in a year, this will be reported to the Internal Revenue Service (IRS) as income.

CONFIDENTIALITY

Research records will be kept and accessed by the investigators for a minimum of seven years. The computers that store any data that is collected are password and firewall protected. Study related questionnaires and specimens are identified by a unique study number to protect your confidentiality. The link to your name and study number will be kept in a separate, secure location that only the clinical research team has access to. If data from this study is shared with other (outside) investigators interested in infections, the information will be shared without personal identifiers (for example name, date of birth, SSN).

In unusual circumstances, your research records may be inspected by appropriate agencies. The University of Pittsburgh Education and Compliance Office for Human Subject Research (ECO-HSR) may review your identifiable research information (which may include your identifiable medical record information) for the purpose of monitoring the appropriate conduct of this research study. The sponsor of the study or their designee may also review your identifiable research information but only for the purposes of monitoring the conduct and data collected for the study. No information will be extracted from your medical record unless you sign a separate medical release and no information about your participation in this study will be placed in your medical record.

We will do everything possible to keep your test results confidential but this cannot be guaranteed. If others would become aware of your HIV status, it could result in discrimination which may impact your employability, insurability, or even prevent you from traveling to certain countries. If you test positive, Pennsylvania state law requires your name and results be reported to the local health department. All information will be handled in compliance with the Pennsylvania law on HIV-related confidential information.

If you test positive for gonorrhea, chlamydia, or HIV, the Commonwealth of Pennsylvania requires that your name be given to the Allegheny County Health Department. You may be contacted and asked questions about your sexual partner(s).

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://www.clinicaltrials.gov. 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.

Your participation in this study may include whole genome sequencing. Whole genome sequencing is the mapping out of a person's unique DNA. Your genome is the unique blueprint for your body. Sometimes, because of new or inherited genetic mutations, your genes can cause a disease or increase your risk for disease. By sequencing your genome, health professionals can look at the unique variations found in your genes. Some of it matters. Some doesn't matter. Some is still unknown or uncertain.

RESEARCH-RELATED INJURY

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 give up your legal rights by signing this form. The US National Institutes of Health (NIH) does not have a mechanism to provide compensation for research related injury.

HIPAA AUTHORIZATION: We are requesting your authorization or permission to access your protected health information for research purposes. This authorization will be valid for an indefinite period of time. We may obtain information concerning your birth control method, age, level of education, past medical and gynecologic history and results of any tests that were already done as part of your standard evaluation.

This information may be needed so that we can compare the data in your medical record to the data obtained for this study. We may use the information to identify whether you meet the conditions for participation in this study. We may also use your medical record to obtain new contact information for you while you are in the study. The information may be needed for retention purposes.

The identifiable information will be made available to members of the research team, for an indefinite period of time and may be shared with other groups, possibly including authorized representatives of the sponsor of the study, National Institutes of Health (or authorized representative that they delegate, such as representatives from monitoring or auditing companies) or authorized officials from the University of Pittsburgh Office of Research Protections. We will protect your privacy and the confidentiality of your records, as described in this document but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.

Your research information and data may be shared with investigators conducting other research. The shared information may be labeled by your unique study number and linked to the study data that matches the unique study number. The link between your personal identifying information and the unique study number is maintained by the clinical research team and will not be shared with other investigators or laboratory staff.

You can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up to that point will continue to be used by the research team.

YOUR RIGHTS AS A RESEARCH PARTICIPANT/VOLUNTEER

Your participation in this research study is entirely voluntary.
You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh, your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

CERTIFICATE OF CONFIDENTIALITY:
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for the information that must be disclosed in order to meet the requirements of the US Food and Drug Administration (FDA) and other regulatory authorities.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

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.

CONSENT FOR FUTURE USE
As part of this study, there will be samples that are collected specifically for future use and there may also be leftover samples from the main testing that could be stored for future use. These samples may be used by investigators for future research on genital tract infections, for further understanding of STDs and how the body responds to infection and/or genetic testing and may include whole genome sequencing. Whole genome sequencing is the mapping out of a person's unique DNA. Your genome is the unique blueprint for your body. Sometimes, because of new or inherited genetic mutations, your genes can cause a disease or increase your risk for disease. By sequencing your genome, health professionals can look at the unique variations found in your genes. Some of it matters. Some doesn't matter. Some is still unknown or uncertain.

The specimens would be stored at Magee Womens Research Institute by study number; your name will not be on the sample. Information linking your study number to your name will be kept in a separate, secure location in the clinical research area.

Your data or specimens used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or outside agencies may receive.

You would not be informed of results of the future tests since the data may not be applied to a clinical setting and may not affect clinical care. Any results from the research done on future use samples would not be put in your medical record and would be kept confidential. Samples may be given to other investigators (secondary investigators), other than Magee investigators. If samples were given to secondary investigators they would be made available without links to your personal identifying information.

There are few risks to you from future use of your specimens. The risks associated with genetic studies include the potential for a breach of confidentiality which could affect future insurability, employability, or reproduction plans, or have a negative impact on family relationships and/or result in paternity suits or stigmatization. Reports about research done with your specimens will not be put in your health record, but will be kept with the study records. Results from future research using your specimens may be presented in publications and meetings, but your name will not be identified. Data, samples, and genetic data generated from samples may be shared with other researchers and with federal repositories, de-identified.

A federal law, called the Genetic Information Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:

Health insurance companies and group health plans may not request your genetic information that we get from this research. Health insurance companies and group health plans may not use your genetic information that we get from this research when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

PLEASE <u>INITIAL</u> YOUR CHOICE BELOW (chose one):

_____ I agree to the future use of my specimens as described above
initials

OR

_____ I DO NOT agree to the future use of my specimens as described above
initials

PLEASE INITIAL WHICH, IF ANY, OPTIONAL RESEARCH PROCEDURES YOU AGREE TO BELOW:

Optional Procedure	Visit	Timepoint(s)	Initial if you agree
Up to two additional vaginal swab(s)	V2 Enrollment	1, 2, 3, 4, 5, 6 hrs after film placement	
One additional blood sample	V2 Enrollment	1, 2, 3, 4, 5, 6 hrs after film placement	

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VOLUNTARY CONSENT

The above information has been explained to me and all of 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.

_____
Printed Name of Participant

_____ _____ _____
Participant Signature Date Time AM/PM

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