Title: Impact of Hormonal Contraception on HIV acquisition and transmission risk.

Informed consent document date: July 10, 2017

NCT Number: NCT02357368

Emory University and Grady Health System
Consent to be a Research Subject And HIPAA Authorization

Title: Impact of Hormonal Contraception on HIV acquisition and transmission risk.

Short Title: HC-HIV

Principal Investigator: Lisa Haddad, MD., MS., MPH

Sponsor: National Institute of Health

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:
- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

Study Overview
This study is about birth control. We want to learn how different types of birth control can affect your ability to fight off infections. We will measure different types of immune cells in your vagina before and after you receive your birth control method. We will also look at the bacteria and infections in your vagina. Bacteria normally are in the vagina, and immune cells fight infection. We will also study how other things (such as age and behavior) can affect the amount of bacteria and immune cells in your vagina. We hope to learn more about how different people can get infections, such as HIV.
You were asked to be in this study because you are a healthy female between the ages of 18 and 45 years and have decided to receive one of the following for birth control:
- The contraceptive injection or shot (Depo Provera)
- The contraceptive implant (Nexplanon)
- A hormonal IUD (intrauterine device) (Mirena)
- A copper IUD (intrauterine device

Procedures
Where is the study taking place, and how long will the study last?

- Most of the research procedures will be conducted within the Grady Memorial Hospital (GMH) Clinics. Specifically within the Grady Family Planning and Wellness Clinic or the Infectious Disease Program (IDP) Ponce Clinic
- You could be in the study approximately 17 weeks, (starting from your date of enrollment into the study), as long as you are willing to participate and are continually eligible for being included within the study.

What will I be asked to do?
If you are interested in the study you will undergo a screening visit. For the screening visit, you will be asked to do the following:

Screening visit: May be scheduled to occur on the same day as your entry visit

You will be asked to:

- Sign the combined informed consent-HIPAA form
- Participate in the study for 17 weeks, with a total of 4 study visits.
- To provide a urine sample for a pregnancy test.
- Answer questions about your medicines and sexual behavior during a brief questionnaire.
- Undergo a medical evaluation (including a pelvic exam and a mouth swab test for HIV that doesn't require blood) to determine if you are eligible for the study based on the study's criteria.

This visit will last approximately 1 hour

If the screening visit shows that you can be enrolled in the study, and you choose to continue, this is what will happen next:

Entry Visit/First Study Visit (week 1): This may occur on the same day as your screening visit

- You will be officially registered into the study
- An interviewer will work with you to respond to questionnaires.
- You will be asked to provide a urine sample for a pregnancy test.
- Pelvic exam will be performed to collect fluid and/or cells from the vagina and cervix We will measure the pH (how acidic or basic) in the vagina is, with an instrument called a pH meter
- Three vaginal swabs will be rubbed on the vaginal wall and tested for bacteria or infections present in the vagina.
- One swab will be rubbed in your anal opening to evaluate the bacteria in your gut
- Diluted vaginal fluid will be collected by squirting and re-collecting some sterile fluid in your vagina.
- Three tubes of blood (about 6 teaspoons) will be collected from your arm.

This visit will last approximately 1 hour

- You will be asked to return for your second study visit two weeks after this visit.

Second Study Visit (week 3): The second study visit will occur two weeks after the first visit

- Answer a brief questionnaire about your medicines and sexual behavior since the last study visit.
- You will be asked to provide a urine sample for a pregnancy test.
- Pelvic exam will be performed to collect fluid and/or cells from the vagina and cervix We will measure the pH (how acidic or basic) in the vagina is, with an instrument called a pH meter
- Three vaginal swabs will be rubbed on the vaginal wall and tested for bacteria or infections present in the vagina.
- One swab will be rubbed in your anal opening to evaluate the bacteria in your gut
- **If you agree** we will collect one or more pieces of tissue from your cervix and vaginal biopsy)

- Diluted vaginal fluid will be collected by squirting and re-collecting some sterile fluid in your vagina
- Two tubes of blood (about 4 teaspoons) will be collected from your arm.
- At this second study visit you will receive the birth control method you have chosen: the injection, the implant or the copper or hormonal UD.

This visit will last approximately 1 hour

Third Study Visit (week 15): The third study visit will occur twelve weeks after the second visit

- The third visit will be like the second study visit.
- If you chose the injection for contraception, you will get your second injection at this visit.
- This visit will last approximately 1 hour.

Fourth Study Visit (week 17): The fourth study visit will occur two weeks after the third visit.

- The fourth visit will be like the second and third study visit.
- **If you agree** we will collect one or more pieces of tissue from your cervix and vagina (cervical biopsy and vaginal biopsy)

This visit will last approximately 1 hour.

For EACH visit, you will be asked to the following:

1. Not have vaginal sex on the day before or the day of your study visit.
2. Reschedule your visit if you have your period on the day of a study visit

All sample collections, blood draws and-physical examination will be performed by qualified study personnel.

Your samples will be stored at the lab. This lab will keep your samples safe and secure for testing during the study. No one besides the Emory Researchers on this study will be able to tell that these samples came from you. The samples stored at the lab will not have any data written on them that could identify you other than a code number. They will not have records stored with them that could identify you.

After the study ends your samples will be destroyed, **unless you agree** for them to be stored for future research.
If you agree, these stored left over samples may be used as a source of DNA for genetic testing that is not yet planned but may be done at a later date. This testing may include studies of HIV, studies of other diseases that affect people with HIV, studies of your cells, proteins, and other chemicals in your body, and studies of your DNA.

If you allow us to do these additional tests on your specimens, these specimens will be kept confidential. They will be stored in a building that is secure. They will not be stored together with information that could let someone know that they came from you. All your specimens will be labeled with a unique code and your name will not be written on any specimens.

More information about this is in the optional sample storage consent section that is within this consent form.
You do not have to agree to this optional storage and use of your left over samples in order to be in the main research study.

Explanations Of The Study Procedures Are Outlined Below:

Vaginal Biopsy
A vaginal biopsy takes one or more samples of tissue from the vagina. The vulva is the outer parts of the female genitals, including the labia, which are often called the lips, and the clitoris. The vagina is the opening that leads to the cervix, which is the entrance to the uterus.

Cervical Biopsy
A cervical biopsy involves taking takes one or more small samples of tissue a small tissue from the certain areas of the cervix. Biopsy may cause mild discomfort, bleeding or cramping.

Why is a cervical or vaginal biopsy needed?
A biopsy is done to collect additional tissue that can be tested in the future for different markers that can impact your body's ability to fight infection

What happens during the procedure?
The biopsy area will be cleaned with an antiseptic liquid. Your provider will use a speculum to open your vagina. A speculum is the same instrument used during a Pap smear. Numbing medicine may be injected into the area that is going to be biopsied. One or more small pieces of tissue will be removed and sent to a lab for analysis. If you require stitches, dissolvable stitches will most likely be used, which do not need to be removed by your provider. You may feel some discomfort and pressure during the procedure.

What should I expect during recovery?
- You may bathe or shower as soon as you want after the procedure.
- You may have some bleeding, spotting or discomfort after the procedure.
- You may have some bleeding, spotting or discomfort after sex

Risks and Discomforts
There may be side effects from the study drug or procedures that are not known at this time.
This study does not involve any therapeutic intervention with biologic products. The protocol does require the collection of sensitive and confidential information (sexual habits, contraceptive use, antiretroviral medication use, and pregnancy status/history), as well as biological samples (blood, biopsies, genital swabs/lavages).

As with any study that includes these procedures there may be side effects from the study procedures that are not known at this time. However, for those common risks and discomforts expected in this study they are outlined in the consent forms, and also listed below with the methods to minimize any associated risk:

1: **Interview/Screening and follow up interview questions:**
Assessment of sexual behavior will be done at each visit using a brief questionnaire. The responses to these questions may make one uncomfortable.
All interviews will be done in private room, with adherence to protecting the privacy and the confidentiality of data through the use of trained interviewers and other study staff.

2: **Physical exams (Pelvic exam):**
Gynecologic and pelvic examinations may cause both physical and emotional discomfort. Though mild discomfort and spot bleeding may occur in the area may during or just after the examinations, there are no known serious adverse effects expected and only experienced health care practitioners will conduct the pelvic examinations. The pH meter may feel cold on when first inserted into the vagina, but no serious adverse events are expected with its use. For the pelvic examination, no known serious adverse effects are expected and they will be done only by experienced health care practitioners.

3**: Risk of Drawing Blood (Biologic Sample collection):**
The needle used to collect blood may cause a bruise at the insertion site, and in very rare circumstances, an infection may develop. Other uncommon risks related to the blood draw include pain, bleeding, blood clots, discomfort, swelling, light-headedness, and fainting. Blood will be drawn by an experienced health care practitioner and universal precautions will be employed in all instances involving human specimens and samples.

4: **Biologic Sample collection (Urine, vaginal/endocervical swabs, and lavage):**
Mild discomfort in the area may occur during examinations and lavage washing procedures. However, there are no known serious adverse effects expected and only trained and experienced health care practitioners will conduct these collection procedures.

5: **Tests assessments/determination of pregnancy status, sexually transmitted infection (STI) and/or vaginitis:**
Experience health care practitioners will perform all tests, examinations and counseling.

If a test result is positive, thus indicating the presence of an STI or vaginitis, individuals may experience emotional discomfort upon receiving their diagnosis, or upon notifying sexual partners, as this would be recommended by study staff during counseling. If you have an infection, a qualified health care practitioner will give participants counseling, and referral to a clinician for further testing and/or treatment.

Though subjects will be on contraceptives during the course of the study, a pregnancy test will be administered at each visit. Should a participant be found to be pregnant in the process of screening or during the study they will be given referrals to medical care and the necessary education. Referrals will include: prenatal care, adoption and abortion care services.

Furthermore this study requires documentation of HIV infection status. All staff participating in these studies are trained in the provision of HIV pre- and post-test counseling in accordance with the standards set out in the US department of Health and Human Services HIV Counseling, Testing and Referral Standard and Guidelines. HIV test counseling and HIV risk behavior counseling will be provided to all potential participants and to those volunteers enrolled in the study. Should a volunteer be found to be infected with HIV in the process of being screened or during the study, they will be given the necessary referrals for medical care, and education about reducing their risk of transmitting HIV to others. Such referrals will include several alternate sources of care, and information about how to become enrolled and engage in such care.

6: **Contraceptive use:**
Individuals will select their method of contraceptive. These are FDA approved methods readily available in the market for purchase. Routine risks or side effects for each method of contraceptive are clearly outlined within the safety and precaution data sheets. Other risks of discomfort may also occur during injections, insertion of the IUD or the Implant.
For all methods of contraception, a qualified health care practitioner will give the participant appropriate counseling on the method chosen and discuss all potential side effects as listed on the FDA regulated inserts for the method of contraception prior to starting the contraceptive. As part of clinical practice, for the contraceptive implant and IUD, your provider will review the specific risks of that contraceptive with you in a separate consent form.

7: **Pregnancy Risk:**
There is a risk that you may get pregnant while enrolled in the study. This risk is the greatest during the first few weeks of the study before you start your contraceptive. You will be asked to either abstain from sex or use condoms during this time to reduce your risk of pregnant. If you get pregnant during the study, we will refer you for further care.

8: **Risks of Sample Storage:**
There are few risks related to storing your samples. The greatest risk is to your privacy. It is possible that if others found out information about you that is learned from tests (such as information about your DNA), it could cause you problems with family members (having a family member learn about a disease that may be passed on in families or learning who is the true parent of a child) or problems with getting a job or insurance.

9: **Risks of cervical and vaginal biopsy:**
Mild discomfort and pressure in the area may be felt during the collection of the tissue. Also, there may be some mild discomfort, cramping and mild bleeding after collection of the samples.
Call your provider if you experience:

- Redness, swelling and skin that is warm to the touch in the biopsy area
- Fever (100.4oF or greater) in the 10 days following the procedure
- Foul-smelling vaginal discharge
- Heavy vaginal bleeding

New Information
It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits
This study is not designed to benefit you directly. Your physical health will be assessed at each visit and it may improve while you are in this study. However this cannot be guaranteed. If you have an infection, we will refer you to a clinician for further testing and/or treatment. However, the study will not pay for the treatment or any extra tests. Additionally, if a medical question, issue or concern is discovered as a result of your physical exams, or from your biological sampling, you will be notified, and the information will be provided to your Primary Care Provider or clinician of your choosing or we can refer you to a provider who can provide further testing and/or treatment.

Compensation
You will receive $50 for the initial screening visit.
If accepted into the study you will receive $50 for the entry visit and for every follow up visit that you complete, for the duration of the study.
This means that if you complete the screening and all 4 visits, you will receive a total of $250.

Payment is conditional on you completing each stated visit requirement.

On completion of the study (when all participants have been enrolled and completed all 4 study visits), if you arrived on time (no later than 10mins) for each of your 4 study visits and have completed all 4 study visits, you will be entered into a raffle for a $200 gift card.

What other choices do I have if I do not take part in this study?
Your decision to participate in this research study is entirely voluntary. You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you, and it will not influence your care. You may also decide to participate now, but withdraw your consent later and stop being in the study without any loss of medical care to which you are entitled.

Other Treatment Outside this Study

If you decide not to enter this study, there is care available to you outside of this research. The study doctor will discuss these with you. You do not have to be in this study to be treated by these medical care providers.

Confidentiality
Emory will keep any research records that it creates private to the extent that this is required to do so by law. 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.

Medical Record
If you are or have been a Grady Health System patient, you have a Grady Health System medical record. If you are not and have never been a Grady Health System patient, you do not have one. A Grady Health System medical record will be made for you if the facility gives you any services or procedures for this study. Copies of the consent form/HIPAA authorization that you sign will not be put in your Grady Health System medical record.

Grady Health System may create study information about you that can help with your care. For example, the results of study tests or procedures, or notes regarding the procedures for contraception placement or any abnormal findings noted on examinations. These study results may be put in your Grady Health System medical record. 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.

Grady Health System does not control results from tests and procedures done at other places, so such results will not be placed in your Grady Health System medical record. They will likely not be available to Grady Health System to help take care of you. Grady Health System does not have control over any other medical records that you may have with other healthcare providers. Grady Health System will not send any test or procedure results from the study to these providers. If you decide to be in this study, it is up to you to let your health providers know.

The researchers will review the results of certain study tests and procedures only for the research. The researchers **will not** be looking at the results of these tests and procedures to make decisions about your personal health or treatment.
Authorization to Use and Disclose Protected Health Information
The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

Authorization to Use and Disclose Protected Health Information

Main Study
PHI that will be Used/Disclosed:
The PHI that we will use and/or disclose (share) for the research 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 PHI will be Used/Disclosed:
We will use and disclose your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry

out the study, such as data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. No PHI will be shared with the CDC or CDC affiliated laboratory, with regards to this study. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

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

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the study, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People that will Use and/or Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Grady Health System may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- NIH is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that involved in study administration and billing. These include the Emory IRB, Western IRB, and other IRBs or privacy boards involved in this study; the Emory Research and Healthcare Compliance Offices; and the Emory Office for Clinical Research.
    - Offices of the Grady Health System that are involved in the study administration and billing.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
    - The National Institutes of Health (NIH)
    - The research team of Dr. Lisa Haddad at Emory University in Atlanta, GA.

<u>Optional Storage of Samples and Contact for Future Research</u>:

PHI That Will be Used/Disclosed for Optional Storage of Samples and Contact for Future Research:
The PHI that we will use and/or disclose (share) for the optional storage and Contact future research use of you additional and left over samples 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 PHI will be Used/Disclosed for Optional Storage of Samples and Contact for Future Research:
We will use and disclose your PHI for the conduct and oversight of the optional the optional storage and future research use of your additional and left over samples.

Authorization for This Use of PHI for the Optional Storage of Samples and Contact for Future Research:
You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional storage of any additional or left over study samples, then you may not participate in the optional storage. You can still be in the main research study even if you don't participate in the optional storage section.

People Who Will Use/Disclose Your PHI for Optional Storage of Samples and Contact for Future Research:
The following people and groups will use and disclose your PHI in connection with the optional storage of additional and left over sample for future research use:

- "The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the PHI for future research using your additional and left over samples"

Expiration of Your Authorization
This authorization will not expire because it is a research study.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must write to Dr. Lisa Haddad.

Other Items You Should Know
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers or health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.
To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI 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. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations and/or for other purposes besides this study.

<u>In Case of Injury</u>
All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications (illness or injury) from participating in this study. In the event that you have an illness or injury that is directly caused by your participation in this study, the Protocol Director and the research study staff will assist in referring you for the appropriate medical treatment from the Emory, Grady Health System or an outside provider.

Emory, Grady Health System, and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proved that your illness or injury is directly caused by the negligence of an Emory, Grady Health System, or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this trial, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Haddad. You should also let any health care provider who treats you know that you are in a research study

Costs

The study sponsor will pay for certain items and services that you may receive if you take part in this study.
The study will pay for those services, supplies, procedures, and care associated with this study that are not a part of your routine medical care. Costs associated with routine medical treatment or management is not covered by this study. The costs for your contraception **will** be covered by this study. The study will not be paying for contraceptive care needed after completion of study activities. Participation in this study is not a substitute for health insurance. You and/or your health insurance must pay for those services, supplies, procedures, and care that you require during this study for routine medical care. You will be responsible for any co-payments and/or deductibles as required by your insurance.

You will have to pay for the items or services for which the study sponsor does not pay. As the sponsor will not pay for your regular medical care, Emory and Grady Health System will submit claims to your insurance (if you have insurance) for items and services that the sponsor does not cover. Emory and Grady Health System will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance, and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory, Grady Health System, and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory and Grady Health System will review your case as part of their programs for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. If you leave the study before the final planned study visit, the researchers may ask you to have some of final steps done.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- The Protocol Director decides that it is in your best interest to discontinue your participation in the study;
- Failure to follow the instructions of the Protocol Director and study staff;
- You were to object to any future changes that may be made in the study plan;
- Pregnancy;

- You need treatment not permitted within the study;
- The study is cancelled;
- Unanticipated circumstances;

Or for any other undefined reason.

Contact Information

Contact Dr. Haddad:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu

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Consent

Please print your name and sign below if you agree to be in this study. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent form to keep for your records.

_____

Name of Participant

_____ _____ _____

Signature of Participant **Date** **Time**

_____

Name of Person Conducting Informed Consent Discussion

_____ _____ _____

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

Attachment 1 of Consent Form

Sample Storage and Future Testing

Please carefully read the statements below and think about your choices.
No matter what you decide, it will not affect your care or your ability to participate in the study.

If you agree, left over de-identified samples will be stored and may be used for further tests.
The research using your left over samples will be done at a later date and may include genetic testing.
It is not our policy to provide any payment or financial benefit for use of these left over samples.
Your stored samples will be labeled only with your study number, and not your name.
Storage of leftover samples is not a requirement to take part in the study.
You may withdraw your permission for the storage of your left over samples at any time. If you want your left over samples destroyed during the study or after you have finished the study, you should call the study doctor or nurse and ask that these samples be destroyed at 404-778-1385.

If you agree, these samples may be held for an indefinite time period, until it is used up or destroyed.
We cannot ensure that you will be told of the results of the research done on theses samples.
The information that is obtained from the analysis of your samples may be used for scientific research purposes. The analysis of your samples may contribute to the creation of new diagnostic tests, treatments, drugs, or other products. In some instances, these may have potential commercial value.
You will not receive any financial benefits, or rewards, nor will you receive any health-related benefits from such developments.

If you want your left over samples destroyed during the study or after you have finished the study, you should call or write the study doctor or nurse, and ask that these samples be destroyed.

_____ **I Agree** to have to have any of my left over samples (blood, any other bodily fluid, swab or tissue biopsy specimen) stored and used for additional research purposes. I understand that this research will be done at a later date and may include genetic testing.

_____ **I Do Not Agree** to have to have any of my left over samples (blood, any other bodily fluid, swab or tissue biopsy specimen) stored and used for additional research purposes.

_____
Name of Participant

_____ _____ _____
Signature of Participant **Date** **Time**

_____
Name of Person Conducting Informed Consent Discussion

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

Attachment 2 of Consent Form

Contacting Research Subjects For Future Studies

Please carefully read the statements below and think about your choices.
No matter what you decide, it will not affect your care or your ability to participate in the main study.

If you agree, you may be contacted for future studies.

Please initial below whether you agree to be contacted by the Principal Investigator or Research Staff regarding future studies.

Do you give your permission to be contacted in the future by the Principal Investigator or Research Staff regarding your willingness to participate in future research studies about the contraceptives you have received during your study participation?

☐ **YES, I agree to be contacted** _____**Initials**

☐ **NO, I do not want to be contacted** _____**Initials**

_____
Name of Participant

_____ _____ _____
Signature of Participant **Date** **Time**

_____
Name of Person Conducting Informed Consent Discussion

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

Attachment 3 of Consent Form

Optional Consent Form for Cervical and Vaginal Biopsy Collection

Please carefully read the statements below and think about your choices. No matter what you decide, it will not affect your care.

If you agree, we will collect one or more small pieces of tissue from your cervix and vagina.

Prior to the study procedure we will clean the area with an antiseptic liquid and may apply a small amount of numbing medication (0.5-1ml of 1% lidocaine). You may experience some cramping or discomfort during the biopsy. After the biopsy is performed, we may apply some silver nitrate to stop the bleeding or use a suture. If we need to use a suture, this will dissolve on its own without requiring removal.

Your stored samples will be labeled only with your study number, not your name. Your stored samples may be used by the current researchers or by researchers at Emory or outside of Emory. These other researchers will not have access to your name or any other information that can identify you.

This collection of cervical and vaginal biopsies are not requirements to participate in the study. These de-identified samples may be held for an indefinite length of time. We cannot ensure that you will be told of the results of the research done on these samples. The information that comes from the analysis of your biopsies may be used scientifically. The results may contribute to the creation of new diagnostic tests, or other uses that may be commercially valuable. There are no plans for you to receive any financial benefits or any health-related benefits from such developments.

YES, I agree to participate in the collection of one or more pieces of tissue from my vagina _____**Initials**

No, I do not agree to participate in the collection of one or more pieces of tissue from my vagina _____**Initials**

_____
Name of Participant

_____ _____ _____
Signature of Participant **Date** **Time**

_____
Name of Person Conducting Informed Consent Discussion

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