RESEARCH PARTICIPANT INFORMED CONSENT
AND PRIVACY AUTHORIZATION FORM

Protocol Title: Duration of Hormonal Contraceptive Use: Immune Responses & Vaginal Microbiota

Application No.: NA_00043112

Sponsor: National Institutes of Health (NIH)
Johns Hopkins Bayview Institute for Clinical and Translational Research - Clinical Research Unit (ICTR-CRU)

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1. **What you should know about this study:**
   - You are being asked to join a research study.
   - This consent form explains the research study and your part in it.
   - Please read it carefully and take as much time as you need.
   - Please ask questions at any time about anything you do not understand.
   - You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or quit at any time. There will be no penalty or loss of benefits if you decide to do either.
   - During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
   - Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.

2. **Why is this research being done?**
   This research study is being done to try and understand how the duration of hormonal contraceptive use (for example, birth control pill, vaginal hormonal ring or Depo Provera shots) impacts the community of normal healthy bacteria in the vagina and the lower genital tract’s immune defenses.

Women 16 to 35 years old may take part in this study. However, women with the following conditions are not eligible for this study:
   - Women who are pregnant
   - Women who are diabetic;
   - Women who have had a hysterectomy;
Women who have specific problems with their immune systems; or
Specific problems with their hormone cycles.

We are recruiting two groups of women so that we can compare both groups:
a) Women who are starting or already using hormonal contraceptives and
b) Women who are not using hormonal contraceptives

**How many people will be in this study?**

We expect about 390 women will take part in this study at Johns Hopkins:
- 240 women who will be starting hormonal contraceptives and
- 150 women who are not planning on using hormonal contraceptives

3. **What will happen if you join this study?**

If you agree to be in this study, we will ask you to do the following things:

- During the first visit (today), you will be seen by your regular doctor as scheduled. In addition to the routine care that all patients usually get, you will also be asked:
  - Some additional questions about your previous and current medical history, and questions about your daily lifestyle habits
  - To provide an additional 6 tablespoons of blood, 1 tablespoon of saliva and some urine, as well as 5 vaginal swabs, 1 swab from the outside of the cervix, 2 swabs from the inside of the cervix and 1 (optional) rectal swab. Your doctor will obtain all these specimens.

Please check the appropriate box below about the collection of rectal swab sample:
- YES: I do agree to the collection of rectal swab for the purpose of this research study
- NO: I DO NOT agree to the collection of rectal swab for the purpose of this research study

- You will be asked to return for seven (7) follow-up visits over the next 2 years. The schedule of these visits is as follows:
  - 2 weeks
  - 1 month
  - 3 months
  - 6 months
  - 12 months
  - 18 months
  - 24 months

During these follow-up visits, you will be seen by a study clinician at a special clinic on the Johns Hopkins Bayview Medical Center campus. You will not be charged for the visit or any of the tests. During each of these visits, you will be asked:

- Some additional questions about changes in your current medical history and your daily lifestyle habits
- To provide an additional 6 tablespoons of blood, 1 tablespoon of saliva and some urine, as well as 5 vaginal swabs, 1 swab from outer cervix, 2 swabs from the inner cervix and 1 (optional) rectal swab. The study clinician will obtain all these specimens.
Please check the appropriate box below about the collection of rectal swab sample:

☐ - YES: I do agree to the collection of rectal swab for the purpose of this research study

☐ - NO: I DO NOT agree to the collection of rectal swab for the purpose of this research study

► For a period of about two weeks in between follow-up visits, we will ask that you keep a diary about your daily habits during those two weeks. We will also ask that you self-collect 18 vaginal swabs, 6 vaginal smears and 6 vaginal pH measurements during those two weeks and bring these things with you to your next visit. We will teach you how to obtain these specimens.

Please be aware that:

- You can decide to stop or start hormonal contraceptives at any time during this study. We expect that about 35% of participants who start contraceptives will decide to stop using them during these two years. Also, we expect that about 15% of participants who initially don’t want to use contraceptives will decide to start using them. No matter what you decide to do, we will still like to follow you in this study.
- If you have any problems, you can make an appointment to see your regular doctor any time while in the study. This study will not interfere in your routine medical care.

Incidental Findings

Results of pregnancy, STI and HIV testing done at the first visit in the Gynecology Clinic will be shared with your doctor. If the test results are positive, your doctor will provide you with appropriate therapy (this study does not cover the cost of therapy). Depending on the infection, you may need to have your sex partner(s) get therapy as well. We will not repeat these tests during the follow-up visits unless you ask us to repeat them or you are having symptoms at the time. If we repeat these tests at the follow-up visits, we will inform your regular doctor of any positive results.

Most of the other tests that we will run on the specimens you provide us will not be shared with your regular doctor because they are not used clinically.

Future Use of Specimens

We would like your permission to store unused specimens for future testing related to the focus of this study: hormone contraception use and its effects on the lower genital tract.

Please initial your choice below:

_____ I agree to have my specimens stored for future testing.

_____ I do not agree to have my specimens stored for future testing.

Future Contact

We would like your permission to contact you about other studies that you may be eligible for in the future.

Please initial your choice below:

_____ I agree to be contacted for future research

_____ I do not agree to be contacted for future research
How long will you be in the study?
You will be in this study for 2 years.

4. What are the risks or discomforts of the study?
- Blood draw: The needle stick is likely to cause some mild discomfort; it is less likely to cause bruising and unlikely to cause an infection at the site of the stick.
- Cervical and vaginal swabs: The swabs may cause mild irritation and, less likely, mild bleeding.
- Confidentiality: All your information will remain confidential; all the study data will not be linked to your name and will be under lock and key in the lead researcher’s office. However, please note that if your STI/HIV tests are positive, your doctor may need to inform your sex partners so that they may be treated.
- Questions/Questionnaires: You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

5. Are there any benefits to being in this study?
There is no direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

6. What are your options if you do not want to be in this study?
You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?
You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet.

This sheet will give you the following information:
- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

8. Will you be paid if you join this study?
You will be paid $50 for each visit that you complete.

If you complete at least 80% of the follow-up visits and you bring in at least 80% of swabs on time you will receive a $100 bonus check at the completion of the study.

Therefore, you may be paid up to $500 over two years for participating in this study.

We will also cover your parking and transportation fees as necessary.
You may be required to provide your Social Security number to be paid. If your payment for study participation exceeds $600 per year, this information must be reported to the Internal Revenue Service.
9. **Can you leave the study early?**
   - You can agree to be in the study now and change your mind later.
   - If you wish to stop, please tell us right away.
   - Leaving this study early will not stop you from getting regular medical care.
   - If you leave the study early, Johns Hopkins may use or give out your health information that it already has if that information is needed for this study or any follow-up activities.

10. **Why might we take you out of this study early?**
    You may be taken out of this study if:
    - You fail to follow instructions.
    - The study is cancelled.
    - There may be other reasons to take you out of the study that we do not know at this time.

    If you are taken out of the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

11. **How will your privacy be protected?**
    Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy.

    The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and other details.

    Generally, only people on the research team will know that you are in the research study and will see your information. However, sometimes other people at Johns Hopkins may see or give out your information. These include people who review research studies, their staff, lawyers, or other Johns Hopkins staff.

    People outside of Johns Hopkins may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and companies that sponsor the study.

    We cannot do this study without your permission to use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

    We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Hopkins who receive your information may not be covered by this promise. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee this.

    The use and disclosure of your information has no time limit. You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator’s name, address, phone and fax information are on page one of this consent form.
If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

12. **What treatment costs will be paid if you are injured in this study?**
Johns Hopkins and the federal government do not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you, as it is to all sick or injured people.

- **If you have health insurance:** The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- **If you do not have health insurance:** You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

You will not give up your right to seek compensation for harm by signing this form.

13. **What other things should you know about this research study?**
   a. **What is the Institutional Review Board (IRB) and how does it protect you?**
      The Johns Hopkins Medicine IRB is made up of:
      - Doctors
      - Nurses
      - Ethicists
      - Non-scientists
      - and people from the local community

      The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have been treated unfairly. The IRB office number is (410) 955-3008. You may also call this number for other questions, concerns or complaints about the research.

   b. **What do you do if you have questions about the study?**
      Call the principal investigator, Dr. Khalil G. Ghanem at (410) 599-2627. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at (410) 955-3008.

   c. **What should you do if you are injured or ill as a result of being in this study?**
      Call Dr. Khalil Ghanem (410) 599-2627, if you have an urgent medical problem related to your taking part in this study. Also call Dr. Khalil Ghanem at (410) 599-2627, if you think you are injured or ill because of this study.

   d. **What happens to data, tissue, blood and other specimens that are collected in this study?**
      Scientists at Johns Hopkins work to find the causes and cures of disease. The data, tissue, blood and other specimens collected from you during this study are important to both this study and to future research.
If you join this study:
- You will not own the data, tissue, blood or other specimens given by you to the study team for this research.
- Both Johns Hopkins and any sponsor of this research may study any data, tissue, blood or other specimens collected from you.
- If data, tissue, blood or other specimens are in a form that identifies you, Johns Hopkins may use them for future research only with your consent or IRB approval.
- You will not own any product or idea created by the study team working on this study.
- You will not receive any financial benefit from the creation, use or sale of such a product or idea.

e. **What are the organizations that are part of Johns Hopkins Medical Institutions?**
   Johns Hopkins Medical Institutions includes the following:
   - The Johns Hopkins University
   - The Johns Hopkins Hospital
   - Johns Hopkins Bayview Medical Center
   - Howard County General Hospital
   - Johns Hopkins Community Physicians
   - Suburban Hospital
   - Sibley Memorial Hospital
14. **What does your signature on this form mean?**
    Your signature on this form means that:
    - you understand the information given to you in this form
    - you accept the provisions in the form
    - you agree to join this study

    You will not give up any legal rights by signing this form.

    **WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM**

    Signature of Participant: ________________________________________________________________
    Date/Time: ______________________________________________________________________________

    Signature of Study Member Obtaining Form: ______________________________________________
    Date/Time: ______________________________________________________________________________

    **NOTE:** A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; AND, IF APPROPRIATE A COPY OF THE CONSENT FORM MUST BE PLACED IN THE PARTICIPANT’S MEDICAL RECORD.

    **ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO SHOULD BE USED TO CONSENT RESEARCH PARTICIPANTS. IF THIS CONSENT FORM DOES NOT HAVE A JOHNS HOPKINS MEDICINE LOGO, DO NOT USE IT TO CONSENT RESEARCH PARTICIPANTS.**