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 the study.
- Please read it carefully and take as much time as you need.
- Ask your study doctor or the study team to explain any words or information in this informed consent that 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 you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- 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.
- If you receive routine medical treatment (including medical or laboratory tests) in the study or if you are taking part in the study at the Clinical Research Unit, information about your research study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes 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 and All Children’s Hospital.
2. Why is this research being done?
This research is being done to study the impact of vaginal childbirth on the pelvic muscles. Our goal is to investigate whether different types of childbirth might affect the muscles differently. Also, we hope to study whether differences in muscle strength and structure impact the development of certain problems, such as vaginal prolapse.

Participants of the Mothers Outcomes after Delivery (MOAD) study may join this research.

How many people will be in this study?
We hope that 1500 women in the MOAD study will join.

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:
1. You will have an ultrasound at the time of your annual MOAD study physical exam. During this ultrasound procedure:
   • You will be in the same position as for a gynecologic examination.
   • The sonographer will put some ultrasound gel on the skin close to the vagina opening.
   • The ultrasound probe will be covered with a plastic sheath or glove and placed on the skin.
   • Light pressure will be applied
   • At least two pictures will be taken, including one picture while you bear down and one while you pull in on the rectal muscles.
   • Each picture will take less than 20 seconds to acquire.
   • After the pictures are taken, you are welcome to look at the images and ask questions about the images.

2. We will measure your pelvic muscle strength.
   • The strength of the muscles is measured with a sensor that goes inside the vagina. The sensor is narrower than the speculum device your gynecologist uses when you go for your pap smear
   • You will be asked to squeeze or tighten the pelvic muscles (as if you were trying to stop urine or gas). The probe measures the strength of the squeeze.
   • Typically, two squeeze efforts are measured.
   • The probe is covered with a Latex glove. Therefore, if you are allergic to Latex, we will skip the measurement of pelvic muscle strength. Also, women who find the vaginal sensor uncomfortable may elect to skip the measurement of pelvic muscle strength.

How long will you be in the study?
You will be in this study for the duration of this MOAD study visit. No additional measurements are planned and no additional follow up is included (other than what is included in the MOAD study).

Incidental Findings
The ultrasound you are having as part of this research study will be reviewed by a qualified person just as it would be if you were having the ultrasound as part of your routine medical care.
There is a possibility that while reviewing your ultrasound we may see an abnormality that we did not expect to see in this study. This is what is called an “incidental finding.”

Because the ultrasound pictures will be obtained from the skin near the vaginal opening, we will not be able to evaluate the uterus or ovaries during the ultrasound. This type of ultrasound does not include an evaluation of those organs. The view will be limited to the pelvic muscles and some portions of the nearby structures, including the urethra, vagina, and anorectum.

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail or by phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding.

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

- An incidental finding may cause you to feel anxious.
- Since an incidental finding will be part of your medical record, it may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility.

4. What are the risks or discomforts of the study?

Ultrasound: This type of ultrasound is used commonly in gynecology and other fields of medicine and is felt to have minimal risk. The process of obtaining this type of ultrasound is expected to produce minimal discomfort. If you find the procedure uncomfortable, we will stop the imaging. In some cases, some women may be embarrassed to have an ultrasound in the vaginal area and you do not have to join the study if you feel you will be too embarrassed.

Pelvic Muscle Strength: The sensor that is used to measure muscle strength is about the same size as the instruments typically used for a gynecologic examination. However, it’s possible that the probe may cause some discomfort in the vaginal area. If this happens, the discomfort is usually mild and goes away right after the examination. Women who find the vaginal sensor uncomfortable may elect to skip the measurement of pelvic muscle strength.

5. Are there benefits to being in the 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 the study?

You do not have to join this study. If you do not join this study, your participation in the MOAD study will not be affected. If you do not join, your current or future care at Johns Hopkins will not be affected.

7. Will it cost you anything to be in this study?

No.

8. Will you be paid if you join this study?

No.
You will receive $50 for being in this study.

You may be required to provide your Social Security number to be paid. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

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 your health information that it has already collected if the information is needed for this study.

10. **How will your privacy be protected?**
    We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your “authorization,” for the use and disclosure of information protected by the Privacy Rule.

    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 information from your medical records. This could include information about HIV and genetic testing, or treatment for drug or alcohol abuse or mental health problems.

    The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

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

    We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. 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 Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

    The use and disclosure of your information has no time limit. You may revoke (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 authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect
information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

11. **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 not been treated fairly. 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. Handa at 410-550-9906 or 410-550-9545. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

   c. **What happens to Data that are collected in the study?**

   Johns Hopkins and our research partners work to understand and cure diseases. The data you provide are important to this effort.

   If you join this study, you should understand that you will not own your data, and should researchers use them to create a new product or idea, you will not benefit financially.
12. **What does your signature on this consent 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 the study

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

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

<table>
<thead>
<tr>
<th>Signature of Participant</th>
<th>(Print Name)</th>
<th>Date/Time</th>
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<table>
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<tr>
<th>Signature of Person Obtaining Consent</th>
<th>(Print Name)</th>
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**NOTE:** A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT’S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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