What you should know:

- 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.
- You are a volunteer. You can choose not to take part and if you join, you may quit at any time. There will be no penalty 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.

Purpose of research project
The purpose of this study is to find out whether learning begins before birth. We are looking at a very basic type of learning that involves the ability to make associations between two different things. In this case, we are trying to find out whether fetuses can make the association between a mother’s change in posture going from a seated to a standing position and a musical sound. We will be able to notice this by how the fetal heart rate changes at different times during the procedure.

Why you are being asked to participate
You are being asked to participate because you are near the end of your pregnancy and you and your baby have not had any problems during this pregnancy.

Procedures
You will come to our Fetal Neurodevelopment Unit located within the Johns Hopkins Prenatal Diagnosis and Treatment Center somewhere between your 35th and 38th week of pregnancy. After we explain the study and ask you some questions, we will place five electrodes on your abdomen in order to record the heart rate signal of both you and your baby. We will also place a round transducer from a standard fetal heart rate monitor to make sure we get a good fetal heart rate signal for your baby. You will sit in a comfortable chair and listen to relaxing music using headphones for about 5 minutes. After this, you will continue to wear the headphones so that you don’t hear the sounds that your baby does. This is to make sure that your baby reacts to the sounds, and not to your responses to them. You will be asked to stand up and sit down a number of times, with a few minutes of rest in between. We will ask you to do this to one type of
sound but not to the other one. At the end we will play both sounds to your baby while you are still wearing the headphones but without standing and sitting to see if they notice this difference. We will be collecting your heart rate and your baby’s heart rate throughout the process. At the end of the procedure we will do a short ultrasound scan to take some measurements of your fluid and see what position the baby is in. The entire visit should last between 1 and 1.5 hours. If you deliver in a hospital other than Hopkins, we will contact you after your baby is born to collect some information about the baby, along with details about your labor and delivery.

**Risks/discomforts**

We don’t expect there to be any risks for taking part in this study. The brief ultrasound scan is not meant to diagnose problems, but in the event that we notice something of concern, such as too little or too much amniotic fluid, we will let you and your physician know. This may result in the need for you to have additional testing by your provider; any costs for additional testing would need to be covered by your insurance or yourself. The electrodes used to monitor you and your baby’s heart rate are similar to those used for heart rate measurement in people who are not pregnant. They do not put electricity into your body. We will need to rub your skin before we put them and this may be slightly uncomfortable. It is possible that the adhesive on them will leave small marks on your abdomen for a short time after they are removed. The round transducer uses sound waves to find your baby’s heart rate and is routinely used in fetal monitoring and labor and delivery. If sitting and standing up makes you feel light-headed or otherwise uncomfortable, we can stop the procedure.

**Benefits**

There are no benefits to you from participating in this study.

**Payment**

In appreciation for your participation, you will be provided with a Target $50 gift card.

**Protecting data confidentiality**

We take protection of your confidentiality very seriously and store your records in a locked location that only some members of the research team can access. When we analyze or publish the results, we will use a number instead of your name and never report information on individual people.

**Authorization for Disclosure of Protected Health Information for research**

We are asking you to authorize the disclosure and use of your private health information for this research study. By signing this authorization, you agree that your obstetrician may release your private health information to us for use in this study if you deliver at Hopkins. Your private health information that we may use for this research includes information about your pregnancy, labor & delivery, and general health.
By signing this Authorization, you permit your obstetrician to release your information to us for use in this research study. We will try to make sure that everyone who needs to see your private information for this research keeps it confidential, but we cannot guarantee this. Although the researchers may not be covered by the Federal Privacy Rule, they will make an effort to protect your information using the same standards.

You do not have to sign this Authorization, but otherwise you may not join the study. It is your choice. Your Authorization does not have an expiration date; it will continue as long as the research continues. You may change your mind and take back this Authorization at any time. If you take it back, the researchers may still use the private health information they have collected about you to that point. To take back the Authorization, you must contact the researcher.

Who do I call if I have questions or problems?

- Call the principal investigator, Janet DiPietro, at 410.955.8536 if you have questions, complaints, or get sick or injured as a result of being in this study.

- Call or contact the Johns Hopkins Bloomberg School of Public Health IRB Office if you have questions about your rights as a study participant. Contact the IRB if you feel you have not been treated fairly or if you have other concerns. The IRB contact information is:

  Address: Johns Hopkins Bloomberg School of Public Health
            615 N. Wolfe Street, Suite E1100
            Baltimore, MD 21205
  Telephone: 410-955-3193
  Toll Free: 888-262-3242
  Fax: 410-502-0584
  E-mail: JHSPH.irboffice@jhu.edu
What does your signature on this consent form mean?

- You have been informed about this study’s purpose, procedures, possible benefits and risks.
- You have been given the chance to ask questions before you sign.
- You have voluntarily agreed to be in this study.

Print name of Adult Participant  Signature of Adult Participant  Date

Print name of Person Obtaining Consent  Signature of Person Obtaining Consent  Date

Give one copy to the participant and keep one copy in study records