The Cleveland Clinic Foundation in association with The MetroHealth System
Consent to Participate in a Research Study
Patient Participant

Study title: Ensuring Patients' Informed Access to Noninvasive Prenatal Testing
Sponsor: National Institutes of Health
Principle Investigator: Ruth M. Farrell. MD, MA; telephone: (216) 444-9275
MetroHealth Site Investigator: Angela Ranzini, MD, telephone: (216) 778-3513
Study Coordinators:
Cleveland Clinic: Christina Collart; telephone: (216) 445 3307
MetroHealth: Bailey Diaz.; telephone: (216) 778-4843
After hours phone contact:
Cleveland Clinic: (216) 444-2200; ask for Dr. Farrell to be paged
MetroHealth: (216) 778-4830; ask for attending or fellows on call

You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

Please note:

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits, and alternatives of the research**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at any time.**

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

There are many prenatal genetic tests currently available to pregnant women, including a new prenatal test called the noninvasive prenatal test or NIPT (you may have heard or seen this test referred to as "Maternity 21" or "MaterniT 21"). This new test can provide information to pregnant women and their partners about the risk of having a child with Down syndrome and other genetic conditions. This test is not recommended for everyone. It is important that women and their partners are able to make informed choices about whether or not they want to use this test or other prenatal genetic testing during pregnancy to find out about the health of the fetus/baby. This test is mainly recommended for women who have increased risk of a genetic condition in the fetus/baby.

Researchers at Cleveland Clinic and MetroHealth are interested in making sure that patients and their partners have the information and help to make informed decisions about whether or not to have prenatal genetic testing including questions about if to use a test like NIPT during their pregnancy. This study is part of learning about how best to help patients and their partners when facing these decisions. This study will gather information about the first prenatal visit between a pregnant woman and her doctor or midwife and will help learn the best ways to discuss prenatal genetic testing with patients.

As part of this study, we are studying different ways for a woman to learn about prenatal testing from her doctor or midwife. One way includes a patient filling out a brief survey before her visit with the doctor or midwife that asks questions about her understanding of different genetic condition and different way to talk about this information during the visit. We call this the NEST instrument. We will provide more information about it below. The other way involves a patient talking to her doctor or midwife about the different testing options without using the NEST instrument. We anticipate that results from this study will help pregnant women and their partners make informed decisions about the prenatal genetic tests that are available to them during pregnancy.

What is involved if you decide to take part in this research study?
If you decide to take part in this research study, you will be asked to complete a survey before your first prenatal care appointment. That survey will include questions about you including your prior experience with prenatal genetic testing and reproductive history. Additionally, you will be asked to complete surveys at three other times: 1) a week after your first visit with the doctor or midwife, 2) soon after you make a decision about your prenatal testing options, and 3) in the second trimester of pregnancy.

One group of participants will be asked to complete another survey, called the NEST instrument. The information from the NEST instrument will be used by your doctor or midwife to help guide discussions about prenatal genetic testing during your appointment.

Your doctor or midwife has been randomly assigned by chance (like a flip of a coin) to one of two groups: (1) to use information from the NEST instrument to guide his or her discussion with the patient about prenatal genetic testing, or (2) to provide counseling about prenatal genetic testing in the usual way. Neither you nor your obstetric care provider will choose which group you are in. This is done by chance because no one knows if one study group is better or worse than the other. <u>Both groups will get the same information from their doctor or midwife, regardless if they are assigned to fill out the NEST instrument before their visit.</u>

If you are assigned to the group asked to use the NEST instrument, you will be asked to complete the NEST instrument before the first prenatal visit. It takes 5 minutes to fill out. After you are done with the survey, a research assistant will print a summary of your responses. One copy will be given to you and the other to your doctor or midwife before your visit. You will receive all of the information routinely provided during the prenatal visit whether you fill out the NEST instrument or not.

After filling out the surveys, you will then proceed with your prenatal visit. As part of this study, we would also like to learn when and how discussions about prenatal genetic testing take place during the first prenatal visit. If you give your written permission (as noted at the end of this document), the research assistant will place a small audio recorder in the examination room to record the discussion that takes place during the visit. We will then use this information to look at what information is talked about during the visit and how it comes up in the visit when patients and their providers talk about their testing options. It will not be used for any other purpose or shared with your doctor or midwife. We will use a transcript or written report of the recorded discussion about prenatal testing. We will not include other parts of the discussion. This written transcript will not contain your name or any other identifying information and will be destroyed at the completion of the research study per Cleveland Clinic records retention policy.

You may choose to participate in both parts of the study: the survey completion and audio-recording part, or only the survey completion. Your participation in either part of the study is voluntary and you may take part in one without taking part in the other.

In addition, a number of participants will be contacted by a Cleveland Clinic research team member to take part in a post study interview. This interview will help the study team at Cleveland Clinic and MetroHealth to learn more about your experience with the NEST study and your decision making processes regarding the different prenatal genetic screening options available to you.

Following your first prenatal visit, women who are in the NEST group and women who are in the standard care group will be asked to complete three other surveys. Each of the surveys takes 5-10 minutes to fill out. The second survey will be sent about a week following your first prenatal appointment. We will contact you between 12 and 22 weeks of your pregnancy to fill out a third survey, and then again between 22 and 24 weeks of pregnancy to fill out a final survey. You will be able to complete the surveys either on paper (for the initial survey or subsequent surveys per request) or online (at a convenient time and location as chosen by you) using a secure web-based link managed by the Cleveland Clinic designed to confidentially collect survey data for research purposes. With your permission, the site specific research coordinator will review your medical record before contacting you for these last three surveys to ensure that you are still receiving prenatal care with your healthcare provider.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

This is a data collection study. The alternative is not to participate. Participation in this study is voluntary. Your decision to participate will not impact your prenatal care. You will receive all of the standard information about pregnancy and prenatal genetic testing whether or not you participate in the study.

3. RISKS

What are the risks of participating in the research study?

There are no physical risks associated with this study. You will not be asked to have any tests or procedures as part of this study. The study questionnaires and NEST will include questions about pregnancy and prenatal genetic testing. These are topics that are commonly talked about as part of prenatal care. Any risks, if they were to happen, may be psychological, such as those caused by worry or concern when thinking about the pregnancy and prenatal tests. There is a chance that some of the questions may cause you to feel uncomfortable. You can decide not to answer those questions.

The information that you share with us during your participation in the study will be kept confidential. No one outside of the research team at Cleveland Clinic and MetroHealth will have access to the information discussed during the visit, the interview (if you decide to be part of the interview) or your survey responses. Your doctor or midwife will see your responses on the NEST instrument because that is part of the study procedures. However, your doctor or midwife will not see your responses to questions asking your opinion on the NEST or the discussion that took place during the appointment. If you happen to mention anything that uniquely identified you during the clinic visit (such as your name, the name of your partner, or child or healthcare provider) we will delete that information from all study materials.

There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential by storing all data collected as part of this study in a password

protected computer accessible only by the research team at Cleveland Clinic and MetroHealth. All members of the research team at Cleveland Clinic and MetroHealth are trained in clinical research compliance which includes how to keep research participants' information private.

Your information will only be used for this study. Cleveland Clinic and MetroHealth will not use or disclose the information collected in this study for any other research purpose without your written permission unless the Cleveland Clinic Institutional Review Board gives permission after ensuring that appropriate privacy safeguards are in place. The Institutional Review Board is a committee whose job is to protect the safety and privacy of research participants.

4. BENEFITS

What are possible benefits of participating in the research?

You may not personally benefit from participating in this study but may help future patients. The knowledge gained from this study will help us understand the impact that NEST has on the discussion that doctors and midwives have with their patients regarding the use of prenatal genetic testing. The information from the research will help us inform obstetric healthcare providers about how to counsel pregnant women about their prenatal testing options.

5. COSTS

Are there any costs to you if you participate in this study?

There are not costs for completing the study surveys.

6. COMPENSATION

Will I be paid for participating in this study?

For your participation in the study you will receive up to $150.00 for your time and effort. This will be paid after completion of the following surveys: Baseline (QBASE, $25.00); Post Visit (QPV, $25.00); Time of Test (QTT, $50.00); and Final Follow-up (QFF, $50.00). All compensation will be sent out through the Accounting Department at the Cleveland Clinic in the form of a research stipend. This will come to you via the U.S. postal service and will be delivered as a check.

The Accounting Department at Cleveland Clinic will be given your name, address, and Social Security Number in order to process payment for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

7. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic and MetroHealth have rules and procedures in place 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 only for the purposes of this study. This includes your health information only as it pertains to this study, data collected for this research study, and personal identifying information including your name, address, date of birth and other identifying information. Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic 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 the sponsor of the research and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing**:** Ruth M. Farrell, MD, Cleveland Clinic, Women's Health Institute, A81, 9500 Euclid Avenue, Cleveland, OH 44195***.*** If you do cancel your permission to use and disclose your information, your participation 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.

This study is a clinical trial since obstetric care providers and their patients will be randomly assigned to either standard care, or use of NEST. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U. S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search the Website at any time.

8. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, you should contact:

Cleveland Clinic: Ruth Farrell, MD, MA at (216) 444-9275. After business hours, you may contact Dr. Farrell by calling the Cleveland Clinic page operator at (216) 444-2200

MetroHealth: Angela Ranzini, MD, at (216) 778-3513. For after hours, weekends and/or holidays, call Labor and Delivery at (216) 778-4830 and ask to speak to the attending or fellow physician on call.

If you have any questions about your rights as a research participant, or if you wish to express any concerns or complaints, please contact the Cleveland Clinic Institutional Review Board at (216) 444-2924.

9. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled.

10. SIGNATURES

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below I agree to take part in this research study as noted below by my selection of the boxes below.

☐ I agree to **complete the study surveys** and **audio-recording** during the visit. (Check box and place initials on the line below)

☐ I agree to **complete the study surveys but I do not agree to audio-recording** during the visit. (Check box and place initials on the line below)

_____
Initials

By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date