COVER PAGE

Study Title: Randomized Clinical Trial of Nurse Family Partnership for Women With Previous Live Births

Document Date: 2/21/2023

**STUDY TITLE: Trial of Nurse Family Partnership for Individuals with Previous Live Births**

## CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

**STUDY TITLE:** ***Trial of Nurse Family Partnership for Individuals with Previous Live Births***

**PRINCIPAL INVESTIGATOR:** ***Deena Chisolm***

**CONTACT TELEPHONE NUMBER: 614.722.6030**

**STUDY SPONSOR:** The National Institutes of Health, National Institute of Nursing Research

**SUBJECT'S NAME: _____ DATE OF BIRTH: _____**

**NOTE: The words "you" and "your" are used in this consent form. These words refer to the study volunteer whether a child or an adult.**

**Key Information About This Study**

We are doing a study to help us decide if a program to support parents and their children improves physical and mental health of the parent and children's development. The program we are testing is called Nurse-Family Partnership (or NFP). In the past, NFP has only been for individuals who are pregnant with their first child. Now we want to know if NFP works to improve health and child development for individuals who have other children. This study involves 'randomization'. This means that a computer will randomly decide whether you receive NFP or other community-based programs and resources. No matter whether you receive NFP or other programs and resources, all individuals who participate in the study will receive a reloadable cash card. The cash card is to pay you for the time it takes to participate in the study. All participants will also receive information about their children's development.

The following is a short summary of this study to help you decide whether to participate. More detailed information follows later in this form.

The purpose of this study is to help us decide if NFP works for improving parent's physical and mental health and children's development for individuals who have other children. This information will help us decide if NFP should be expanded to individuals who have other children. If you agree to participate, a computer will decide if you are offered the NFP program or other community-based programs and resources. The NFP program gives you a free, personal nurse to give you support, advice, and information during your pregnancy and when your baby arrives. The nurse visits with you for up to one hour every one or two weeks. The nurse works with you to find out what is most important to you for your own physical and mental health and your baby's health and gives you information, resources, and support so that you can meet your goals and be the best parent you can be.

Study participation: All participants will be asked to:

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- answer survey questions and do interviews up to 7 times over two and one-half years (30 months),
- be videotaped interacting with their children one time when the child is 18 months old, and
- give saliva (spit) samples two times during pregnancy. (The saliva samples will be tested for cotinine which is a measure of smoking or other tobacco or nicotine use. We are testing for cotinine because we want to see if NFP helps parents who smoke cut down or quit smoking.)
- Children will have their development measured by the study team.

Study visits: Participants will have seven study visits at:

- early pregnancy (before 30 weeks),
- about 36 weeks of pregnancy,
- within 1 month after your baby is born, and
- when your baby is 6 months, 12 months, 18 months, and 24 months old.

Participants will be asked to answer survey questions at all the visits. Participants will be asked to give a saliva sample at two of the visits. The study team will do activities that measure child development at two visits when your baby is 18 and 24 months old. The study team will also look at the home and how you and your baby act with each other at two visits at 36 weeks of pregnancy and when your baby is 18 months old. We would like to do the visits in your home, but we can also do the visits in another location in the community, such as a library, where you feel comfortable. Some visits don't need to be in person and can be done by video or telephone. The study visits will last from 10 minutes to 2 hours depending on what needs to be measured. More information about the study visits is included below.

The main risk(s) of the study are sharing your private information and being asked questions that may make you feel uncomfortable. You do not have to answer any questions that you do not want to answer.

You may or may not personally gain something from being in this study. We hope that the information we learn from this study will help other parents like you.

If you are interested in learning more about this study, please continue reading below.
This study has (a) secondary consent(s) separate from this main study that you may be asked to consider for participation.

## 1) INTRODUCTION

We invite you to be in this research study. Using this form as a guide, we will explain the study to you. If you have any questions about the study, please ask. By signing this form, you agree to be in this study. If you do not want to be in this study, all regular and standard medical care will still be available to you here at Nationwide Children's Hospital. You can choose if you want to be in the study or not. You can leave this study at any time.

You will be given a signed and dated copy of this consent and the assent forms.

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## 2) WHERE WILL THE STUDY BE DONE AND HOW MANY SUBJECTS WILL TAKE PART?

This study will be done at Nationwide Children's Hospital, and we hope to enroll a total of 880 participants. Our goal is for this study to include parents from different backgrounds including different religious beliefs, race, ethnicity, gender identity, and so on. We want to make sure that this study includes the experiences of a diverse group of parents and their children.

## 3) WHAT WILL HAPPEN DURING THE STUDY AND HOW LONG WILL IT LAST?

There will be 7 study visits. Each visit will take 10 minutes to 2 hours depending on what is being measured during the visit. Most visits will be in-person in your home or other community location where you feel comfortable. Some visits can be done by phone or video. The table below shows more information about what will happen at each visit. We will ask you questions about your pregnancy, your children, your home, and your health. The study team will also look at your home, watch how you and your child act with each other, and measure your children's development. Saliva (spit) samples will be collected from you at the two visits during your pregnancy. You can collect these saliva samples yourself with instructions from the research assistant. The saliva samples will be tested for cotinine which is a measure of smoking or other tobacco or nicotine use.

**Summary of Study Visits**

| | | TIMEPOINT | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | **Baseline—before 30 weeks of pregnancy** | **Approximately 36 weeks pregnant** | **Post-partum** | **Child age 6 mo** | **Child age 12 mo** | **Child age 18 mo** | **Child age 24 mo** |
| | **Honoraria** | **$100** | **$75** | **$50** | **$50** | **$50** | **$100** | **$100** |
| | **Estimated Total Time (minutes)** | **90-100** | **80** | **10** | **20** | **15** | **90-120** | **120** |
| | **In-Person or Virtual** | **In-Person** | **In-Person** | **Virtual** | **In-Person** | **Virtual** | **In-Person** | **In-Person** |
| **Activity** | | | | | | | | |
| Parent interview and/or questionnaire | | X | X | X | X | X | X | X |
| Child development assessment | | | X | | | | | X |
| Sibling development assessment | | X | | | | | X | X |
| In-home observation | | | X | | | | X | |
| Parent saliva sample | | X | X | | | | | |

This study is randomized. Randomized means that each participant will be picked by chance, like tossing a coin or drawing straws, to receive either the NFP program or other community-based programs and resources. Each subject has a 50/50 chance of receiving the NFP program and a 50/50 chance of receiving other community-based programs and resources.

This study is blinded. Blinded means that the study team will not know who is receiving the NFP program and who is not.

The NFP program gives you a free, personal nurse to give you support, advice, and information during your pregnancy and when your baby arrives. The nurse visits with you for up to one hour every one or two weeks in person and sometimes by phone or video depending on what you need and want. The

nurse works with you to find out what is most important to you for your own health and your baby's health and gives you information, resources, and support so that you can meet your goals and be the best parent you can be.

If you participate in the study, you will be asked to answer questions about whether you have symptoms of depression and anxiety. If we find that you might have depression or anxiety, we will share this information with you and will give you information about where you can get support. We will also do activities with your children to measure their development. We will share this information with you. If we find that your child may have problems with their development, we will give you information about how you can have your child tested for development problems and receive support for their development if needed. If you ask us to, we can also help you set up follow-up meetings with your regular doctor or other medical professionals not involved in this study who can discuss this information with you. These follow-up visits will not be part of this study, so you and your insurance company would need to pay for any fees and costs related to them.

## 4) WHAT ARE THE RISKS OF BEING IN THIS STUDY?

We believe that there is very little chance that bad things will happen because of being in this study.

It is possible that you could feel upset when answering questions about your diagnosis or medical treatment, but it may be more likely that you find the questions or feedback process a little boring. If you do find any of the questions upsetting or don't want to answer a question, you don't have to.

Although we will be very careful to prevent anyone who is not part of the study from seeing the information we collect, there is a small chance of loss of confidentiality of your study information.

There may be other risks of being in this research study that are not known at this time.

## 5) SPECIAL INFORMATION ABOUT PREGNANCY:

You are being invited to participate in this study because you are pregnant.

## 6) ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

Although there may or may not be a benefit to you from being in this study, we hope to learn something that can improve the lives of others because of the knowledge gained from the parent's experiences.

## 7) WHAT OTHER TREATMENTS OR OPTIONS ARE THERE?

Your participation is this study is voluntary. It is not necessary to participate in this study for you to get care for your pregnancy and your children.

## 8) WHAT ARE THE COSTS AND REIMBURSEMENTS?

We do not expect any costs to you from participating in this study.

You will receive $50-100 per study visit up to a total of $525 if you do all seven study visits. You will be given a debit card specially designed for clinical research. After each study visit, money will be loaded onto your card.

## 9) WHAT HAPPENS IF BEING IN THIS STUDY CAUSES INJURIES?

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We believe that there is very little chance that injuries will happen as a result of being in this study.

**10) WHAT WILL HAPPEN IF NEW INFORMATION IS FOUND OUT ABOUT THE DRUG OR TREATMENT?**

If new information is found out during this study that might change your mind about participating or might affect your health, the study team will tell you about it as soon as possible.

**11) WHAT HAPPENS IF I DO NOT FINISH THIS STUDY?**

It is your choice to be in this study. You may decide to stop being in this study at any time. If you stop being in the study, it will not affect your or your children's healthcare or benefits.

If at any time the Principal Investigator believes that this study is not good for you, the study team will contact you about stopping. If the study instructions are not followed, participation in the study may also be stopped. If unexpected medical problems come up, the Principal Investigator or the Sponsor, the National Institutes of Health, National Institute of Nursing Research, may decide to stop your participation in the study.

**12) OTHER IMPORTANT INFORMATION**

If you are an employee of Nationwide Children's Hospital or the Research Institute at Nationwide Children's Hospital, your job or performance appraisal will not be affected in any way if you decide not to participate or withdraw your consent to participate in this study.

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 this website at any time.

If you are interested, the final study results will be shared with you once they are available. Please provide us with an email or address where we can send these results.

The Principal Investigator is being paid by the National Institutes of Health, National Institute for Nursing Research for the time and knowledge needed to do this study.

Nationwide Children's Hospital is a teaching hospital and we are committed to doing research. Doing research will help us learn and give the best care for our patients and families. You may be asked to participate in other research studies in the future. You have the right to decide to participate or decide not to participate in any future studies. We will not share your contact information with researchers outside Nationwide Children's Hospital.

If you are younger than 18 years old when you start this study, the research team will ask you to review and sign a new consent form when you turn 18 years old.

**13) HOW WILL MY STUDY INFORMATION BE KEPT PRIVATE?**

Information collected for this study includes information that can identify you. This is called "protected health information" or PHI. By agreeing to be in this study, you are giving permission to your healthcare provider to use or disclose (release) your health information that identifies you for the research study

described in this form. Information collected is the property of Nationwide Children's Hospital, its affiliated entities, and/or the sponsor.

Some of the information collected as part of this study will be sensitive, such as information relating to your home environment, mental health, and/or substance use. We will not share this information with anyone unless the research team is concerned that your child is in danger because of exposure to drugs or violence in the home or is being abused. If we have serious concerns that your child is in danger or being abused, we must report our concerns to child protective services.

**PHI that may be used or disclosed will include:**

- Names (individual, child, and relatives),
- Address (individual and relatives),
- Telephone number (individual and relatives),
- E-mail addresses (individual and relatives),
- Birth dates (individual and child),
- Admission and discharge dates and diagnosis for emergency room visits and hospitalizations for you and your child**,**
- Dates of medical visits and diagnosis for prenatal care and well child care for you and your child,
- Your child's weight and gestational age when they are born

**People or Companies authorized to use, disclose, and receive PHI collected or created by this research study:**

- PI and study staff
- The Nationwide Children's Hospital Institutional Review Board (the committee that reviews all human subject research)
- Nationwide Children's Hospital internal auditors
- Other research sites, including collaborators at the University of Colorado
- The study sponsor, the National Institutes of Health
- The Office for Human Research Protections (OHRP) (the federal government office that oversees human subject research)

Because of the need to give information to these people, absolute confidentiality cannot be guaranteed. Information given to these people may be further disclosed by them and no longer be protected by federal privacy rules.

**Reason(s) why the use or disclosure is being made:**
We need to use this PHI so that we can locate your medical records, your child's medical records, and to contact you in the future.

You may decide not to authorize the use and disclosure of your PHI. However, if it is needed for this study, you will not be able to be in this study. If you agree to be in this study and later decide to withdraw your participation, you may withdraw your authorization to use your PHI. This request must be made in writing to the Principal Investigator at Deena Chisolm, 700 Children's Drive, Columbus, OH 43205. If you withdraw your authorization, no new PHI may be collected and the PHI already collected may not be used unless it has already been used or is needed to complete the study analysis and reports.

PHI will only be shared with the groups listed above, but if you have a bad outcome or adverse event from being in this study, the study team or other health care providers may need to look at your entire medical record.

The results from this study may be published but your identity will not be revealed.

A copy of this form and other research related health information may be added to your NCH medical record.

The PHI collected or created under this research study will be used or disclosed as needed until the end of the study. The records of this study will be kept for an indefinite period of time and your authorization to use or disclose your PHI will not expire.

There is a risk that someone could get access to the information we have collected about you. If those data suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. Your privacy and the confidentiality of your data are very important to us. We will make every effort to protect them.

## Publicly Available Scientific Databases

Some of your specimens and genetic and/or health information might also be placed into one or more external publicly-accessible scientific databases. For example, the National Institutes of Health (an agency of the federal government) maintains a database called "dbGaP." Your name and other information that could directly identify you (such as your address or social security number) will never be placed into these external databases. A researcher who wants to study information from these databases must have an approved study and work with the group overseeing the database to obtain the information. Because it is possible to re-identify de-identified genomic data, even if access to data is controlled and data security standards are met, confidentiality cannot be guaranteed,

## Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing

information about your involvement in this research. It also does not prevent you from having access to your own information.

**14) USE OF INFORMATION/SAMPLES FOR FUTURE RESEARCH USE**

Information that identifies you may be removed from your study data and any samples that are collected during this research study and your data and/or samples distributed to other investigators to be used for future research studies without your additional informed consent.

**Future Research Use of Identifiable Information:**

With your permission, we would like to store your identifiable information (including PHI) for future research purposes, and as part of such future research purposes, your identifiable information may be disclosed to people or entities not listed above, such as researchers not involved with this study, government agencies, research foundations, or pharmaceutical or device companies. This future research may or may not be related to your medical problem. This future research may include sensitive information. Any future research projects will be reviewed and approved by an Institutional Review Board which protects the rights, welfare, and safety of human research subjects. If your identifiable information including PHI is used or disclosed in future research studies, absolute confidentiality cannot be guaranteed. Information shared for future research may be shared further with others and no longer be protected by federal privacy rules.

If you decide at any time that you do not want your PHI stored for future research, you must make this request in writing to the Principal Investigator at Deena Chisolm, 700 Children's Drive, Columbus, OH 43205. Once we receive your written request, we will destroy your PHI. However, if we have already shared your PHI with another individual or entity, we will not be able to destroy any of the PHI that are no longer in our possession.

Nationwide Children's Hospital retains the right to cease storage and destroy the PHI at any time without sending notice to you or obtaining your consent.

You do not have to agree to use of your PHI for future research in order to be in this study, and your decision will not affect the care you receive from the study doctors or Nationwide Children's Hospital.

I agree to allow my PHI to be stored and used for future research as described above: (initial)

____ YES ____ NO

**15) WHOM SHOULD I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

If you have questions about anything while on this study or you have been injured by the research, you may contact the Principal Investigator at 614-722-6030, Monday – Friday, between 8am and 5pm.

If you have questions, concerns, or complaints about the research; if you have questions about your rights as a research volunteer; if you cannot reach the Principal Investigator; or if you want to call someone else, call (614) 722-2708, Nationwide Children's Hospital Institutional Review Board, (the committee that reviews all research involving human subjects at Nationwide Children's Hospital).

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## Signature Block for Children ☐ N/A, Adult Subject

Your signature documents your permission for the named child to take part in this research.

_____
Printed name of child

_____ _____
Signature of parent or individual legally authorized to consent to the child's general medical care — Date & Time AM/PM

_____
Printed name of parent or individual legally authorized to consent to the child's general medical care

_____
Relationship to Participant

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact Legal Services if any questions arise.

_____ _____
Signature of second parent or individual legally authorized to consent to the child's general medical care — Date & Time AM/PM

_____
Printed name of second parent or individual legally authorized to consent to the child's general medical care

_____
Relationship to Participant

If signature of second parent not obtained, indicate why: (select one)

- ❑ Not required by IRB
- ❑ Second parent is deceased
- ❑ Second parent is unknown
- ❑ Second parent is incompetent
- ❑ Second parent is not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child

_____ _____
Signature of person obtaining consent — Date & Time AM/PM

_____
Printed name of person obtaining consent

**Assent**

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_____ _____
Signature of subject Date & Time AM/PM

❑ Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.

## Signature Block for Adult Participation ☐ N/A, Pediatric Subject

Your signature documents your permission to take part in this research.

_____ _____
Signature of subject Date & Time AM/PM

_____
Printed name of subject

_____ _____
Signature of person obtaining consent Date & Time AM/PM

_____
Printed name of person obtaining consent