Title: Influence of Prenatal and Early Childhood Home Visiting by Nurses on Development of Chronic Disease: 29-Year Follow-Up of a Randomized Clinical Trial

ClinicalTrials.gov Identifier: NCT06160037

Date: February 15, 2024

Consent and Authorization Form

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Study Title: Influence of Prenatal and Early Childhood Home Visiting by Nurses on Development of Chronic Disease: 29-Year Follow-Up of a Randomized Clinical Trial

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This consent form describes a research study and what you may expect if you decide to participate. Please ask any questions you may have before making your decision about whether you want to participate in this one interview. You are invited to take part in this study because you participated in earlier phases of the New Mothers Study in Memphis, Tennessee. The current phase will help us to learn more about the long-term effects of New Mothers Study services on risks for heart disease, diabetes, and kidney disease in mothers and their first-born children.

If you choose to participate in this interview, we will only ask for your verbal consent. The interview questions will be similar to questions you were asked in the past, and will take about one hour. You will be given $150 for completing the interview. If for any reason based on where you currently are it isn't approved to provide payment directly to you, we can provide it to a person you designate.

We estimate that approximately 1,344 people will take part in this study.

There is a small chance that some of the questions in this interview may make you feel tired or uncomfortable. You may skip any questions you don't want to answer.

There are no other expected risks to you for participating in this study. There are also no expected benefits.

Before you agree to participate, there are some additional things you should know about the study. The University of Colorado and the University of Rochester School of Nursing will make every effort to keep the information collected from you private. In order to do so, we will not attach your name to the interview questions. Your interview will only be identified by a study ID number. Sometimes, however, researchers need to share information that may identify you with people who work for the Universities, regulators or the study sponsor. If this does happen, we will take precautions to protect the information you have provided. Additionally, if you tell us anything during the interview that would cause us to be concerned about you harming yourself or others, we are required to share that information with the jail warden/chief/director/counselor. Results of the research may be presented at meetings or in publications, but your name will not be used. In order to collect study information, we need your permission to use and give out your personal health information. We will use things like your name, birthdate, sex, and address to conduct the study.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed. We will keep the information we collect about you indefinitely.

Your participation in this study is completely voluntary. You are free not to participate or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no

penalty or loss of benefit to which you are entitled. **Your participation in this research will have no effect on any court decisions, parole or probation.**

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

Do you have any questions?

Do you agree to participate in the interview for this study?

☐ _____YES (Interviewer initials) ☐ _____NO (Interviewer initials)

Do you agree to be contacted about future research studies?

☐ _____YES (Interviewer initials) ☐ _____NO (Interviewer initials)

Name of Participant: _____

Person Obtaining Consent
I have read this form to the participant. An explanation of the research was given and questions from the participant were solicited and answered to their satisfaction. In my judgment, the individual has demonstrated comprehension of the information and has provided verbal consent to participate in this study.

Name and Title (Print): _____

Signature of Person Obtaining Consent: _____Date: _____