

Attached to Protocol: TC 18-210
Principal Investigator: Kimberly Noble
IRB Protocol Title: Baby's First Years

Participation Duration: Three Years
Anticipated Number of Subjects: 1,000

Contact	Title	Contact Type	Numbers
Kimberly Noble	MD, PhD	Principal Investigator	(212) 678-3486
Lauren Meyer	Project Director	Administrative	(608) 291-7359

"Baby's First Years" Additional Data: Research Purpose

You have agreed to participate in the research study Baby's First Years and you have agreed to receive a monthly cash gift, deposited on the 4MyBaby card.

We would also like to request your permission to access data on the social services and benefits that your family may be receiving. We are interested in understanding how government social services and benefits that your family receives relate to your day-to-day life. Information about government services and benefits will be collected if you allow researchers to access this information.

Your participation in this component of the study is completely voluntary and will not affect the receipt of the study gift. You will continue to receive the cash gift deposited on the card even if you do not provide your permission to access any additional data.

Information on Additional Data Collected by "Baby's First Years" Study

This form will provide information about the additional components of the study so that you may decide whether or not to participate. This form includes information about:

- Why is additional data collected
- Any known risks
- Any potential benefits
- Available options, other than participating in Additional Components of Baby's First Years
- The things you will be asked to do

I will discuss this request with you and answer any questions that you may have. Take as much time as you need to decide whether you want to grant access to additional data collected by Baby's First Years study.

Purpose of collecting additional data

The purpose of collecting additional information on the types of benefits you and your family receives is to understand how access to social services relates to the day-to-day life of you and your family.

Risks

Confidentiality

Allowing access to additional data may lead to a loss of confidentiality, which entails having your personal information shared with someone who is not permitted to see or know about that information. We will do everything we can to keep the data secure and to make sure your data is not seen by anyone outside of the research team, but we cannot promise complete confidentiality.

Any obtained administrative records will be stored securely on a password protected server at the University of Wisconsin. Unanticipated problems, like a stolen password, may occur, although such incidences are highly unlikely. Our research team will take the utmost care to protect your privacy.

The researchers plan to publish the results obtained from additional data. To protect your privacy, they will not include any information that could directly identify you. They will protect the confidentiality of your research records by assigning a unique participant number to any additional data obtained and never associating your name and any identifying information with any of the collected data. Any data obtained, will be stored in secure data storage at the University of Wisconsin where the data will be processed for use by the research team. The files linking your name to the participant number will be kept in a password-protected database to which only key research staff will have access. When researchers report the study findings they will only report information in general aggregated terms so participants cannot be identified.

Your information collected in this study may be used for future research studies or be distributed to another investigator for future research studies, but it will not have any information that could directly identify you.

The following individuals and/or agencies will have access to the additional data we may obtain:

- Researchers at University of Wisconsin maintaining secure data storage.
- Researchers from University of California – Irvine, Columbia University's Teachers College, New York University, the University of Maryland, Duke University, and University of Wisconsin will use the data for research analysis purposes. Your identity as a research subject will be protected and your name will not be associated with any additional data.
- Authorities from Teachers College, including the Institutional Review Board, and from the Office for Human Research Protection may also access your data

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information protected by this Certificate **cannot** be disclosed to anyone else who is not connected with the research **except:**

- if you have consented to the disclosure;
 - if it is used for other scientific research, as allowed by federal regulations protecting research subjects;
- or

Teachers College, Columbia University
Institutional Review Board

Protocol Number: 18-210
Consent Form Approved Until: 02/13/2021

- if there is a federal, state, or local law that requires disclosure. First, your personal information may be disclosed if we learn that you or someone else is at high or imminent risk of harm. **Secondly, your personal information may be disclosed if we learn of possible abuse of a minor. If a child is in danger of abuse, neglect, or endangerment, we are obligated to report this information to child protection authorities.** If this happens, we will take steps to ensure safety of those indicated.

If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

You and your family must also actively protect your own privacy. If you give consent to anyone else (an insurer or employer, for example) to receive research information, then researchers cannot use the certificate to withhold this information. Researchers must release information as required by Federal, State or local laws, or to prevent serious harm to you or someone else.

Benefits

Although you and your family may not directly benefit from allowing us to obtain records about government services and benefits, others might benefit from research which may be helpful in understanding the effects of income gifts on how children learn and grow.

Alternative Procedures

You may choose to decline our request for additional data and not to participate in this part of the study. You will continue to receive the cash gift deposited on the card even if you choose not to participate in this research study or any future research activities.

Compensation

You will not receive additional compensation for allowing us to obtain government services and benefits records. The monthly gift you will receive is independent of participating in research.

Additional Costs

There are no costs to you for taking part in this study.

Voluntary Participation

Your participation in this study is completely voluntary. Declining to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may choose to stop participating in this research at any time. If you decide to withdraw your permissions, data accessed by the study team will be retained.

The things you are asked to do:

Request for Release of Administrative Records:

We are interested in understanding how other government social services and benefits that your family receives relate to your day-to-day life.

We are requesting to access data on the services and benefits that your family receives. These services and benefits involve the Supplemental Nutritional Assistance Program (SNAP), Temporary Assistance to Needy Families (TANF), Women, Infants, and Children (WIC) Food and Nutrition Service, government funded child care subsidies, child protective services, child support, housing assistance, unemployment benefits, and your reported earnings. Should you choose to participate in any future interviews for this study, your answers will be linked to data in the above systems and benefits.

This will give researchers information about your family's experiences with government services. We will need permission to obtain your family's information collected by government programs and benefits.

Statement of Consent

I have read the consent form about this research study, including the purpose, procedures, risks, benefits, and alternatives. I am aware that by signing below, I agree to take part in this research project. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Please sign here:

Print Name	Signature	Date (mm/dd/yyyy_