**Note to Reader:**

**THIS IS THE BABY’S FIRST YEARS CONSENT FORM LANGUAGE FOR ADMINISTRATIVE DATA**

“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 like to ask for your permission to collect some additional information on when and where you spend the cash gift. The goal of this component of the study is to gain an understanding of how receiving a monthly cash gift might change the experiences of families with new babies. If you decide to participate in this part of the research, information will be collected about when and where, you spend at one time.

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 these components 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 how you spend the gift and information on the types of benefits you and your family receives is to understand where and when your use of the debit card and 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.

All additional data requested from the debit card company and any 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
* 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 track your transactions or 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 track your debit card transactions or obtaining 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:

Requesting more information about your transactions:

You will receive the first payment today on a debit card. You will receive the same amount of cash every month on the day of your child's birth date. If you agree, some information will be collected on when and where you use the card.

We request that you allow the debit card company to provide us with general information including dates, location, and amounts you spend in each transaction. We will collect that information for the entire period when you use the card. The debit card data will not include any information about what you buy.

By initialing below, you agree that the research team can be provided information about use of the debit card from the debit card company.

(initial) Yes, I agree to allow the research team to access information on when and where I use the debit card.

(initial) No, I do not want the research team to access information on when and where I use the debit card.

*Request for Release of Administrative Records:*

We are also 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. Your answers to any interviews conducted as part of this study in which you may choose to participate in the future 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 your permission to obtain your family’s information collected by government programs and benefits and your full or last four digits of your social security number.

(Initial) I agree that the research team has permission obtain information about my receipt of government services and benefit programs.

(initial) I do not grant the research team permission to obtain information about my participation and receipt in government services and benefit programs

Additional Information

A description of this study will be posted on a public website, [http://ClinicalTrials.gov,](http://ClinicalTrials.gov/) and summary results of this study will be posted on this website at the conclusion of the research, as required by the National Institutes of Health (NIH), the study sponsor. No information that can identify you will be posted.

Who to Contact

If you have any questions or concerns about the study, you may contact project director: Lauren Meyer, [bfystudy@gmail.com](mailto:bfystudy@gmail.com), (608) 291-7359, principal investigator: Kimberly Noble, [kgn2106@tc.columbia.edu](mailto:kgn2106@tc.columbia.edu), (212) 678-3486). To report a lost or stolen debit card, contact Lauren Meyer, [bfystudy@gmail.com](mailto:bfystudy@gmail.com), (608) 291-7359, or Greenphire Inc. at the number on the back of your card, on the user tip sheet, or on myclincard.com.

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research. If you have any questions about your rights as a research participant, you should contact the Teachers College Institutional Review Board at:

525 W 120th St

New York, NY 10027

Telephone: (212) 678-3000

Email: [irb@tc.edu](mailto:irb@tc.edu)

More information about taking part in a research study can be found on the Teachers College IR[B website](http://www.cumc.columbia.edu/dept/irb))

<http://www.tc.columbia.edu/institutional-review-board/>

Statement of Consent

I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits, and alternatives with the researcher. Any questions I had were answered to my satisfaction. 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.

Signature

*Study Participant*

Print Name Signature Date

*Person Obtaining Consent*

Print Name Signature Date