

**Note to Reader:**  
This is the Baby's First Years Consent Form for Age 2 Data Collection

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

**Participation Duration:** Three Years  
**Anticipated Number of Subjects:** 1,000  
**Study Sponsor(s):** National Institute of Child Health and Human Development, foundations

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

### Key Information about this research

The goal of this research study is to gain an understanding of the family experiences and backgrounds of families with new babies. Both your and your child's participation in this study is voluntary. The research will last three years in total, beginning when your child was born. There are no direct benefits from participating in this research study, although this study may be helpful in understanding the factors that affect how children learn and grow. The risks for participating may involve boredom or frustration. If at any time you or your child wishes to take a break (for example, a break for feeding or rest), you are free to do so.

This study is sponsored by National Institute of Child Health and Human Development and national and local private foundations.

### Invitation to participate in the Baby's First Years, 2<sup>nd</sup> Birthday Interview

You have agreed to participate in the research study called Baby's First Years. We want to understand the experiences and backgrounds of families with new babies. **Your decision to participate in the 2<sup>nd</sup> birthday interview will not affect the monthly gift you are receiving from the study. You will continue to receive the monthly gift even if you decide not to participate in this interview.**

A University of Michigan interviewer is contacting you on behalf of a team of researchers from the University of California Irvine, Columbia University's Teachers College, New York University, the University of Wisconsin, Duke University, and the University of Maryland to collect information about your baby and family.

### The things we will ask you to do during this 90 to 120 minute interview

We will ask you some questions about you, your family, education, household income/finances; how you have been feeling lately; your romantic relationships; and the last year of your baby's life.

**You can skip any questions that you do not want to answer.**

### Voluntary Participation

Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is complete, your data will be kept confidential. You can participate in the research even if you do not want your child to participate. However, if you choose to not participate, we will not collect information about your child.

**Teachers College, Columbia University**  
**Institutional Review Board**

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### Risks and Burdens

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Risks of participating in this research study to you or your child are minimal. Although rare, the primary risk of participation in this study is from accidental disclosure of your research information. To address this potential risk, identifying information about you is stored separately from your study responses. All data are encrypted and stored securely to help protect your privacy. You may also feel uncomfortable about some questions the interviewer will ask you. You may refuse to answer or skip any question or part of the visit.

There are no direct benefits from participating in this research study. This study may be helpful in understanding the factors that affect how children learn and grow.

### Confidentiality

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Researchers will keep all your personal data private and secure. Your information will not be seen by anyone outside of the research team and will be kept confidential. The researchers plan to publish the results of this study. To protect your privacy, they will not include any information that could directly identify you. Your name will never appear in any publication. 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.

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. For example, 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.

After completing the interview, the University of Michigan will transfer your interview data, to a secure storage at the University of Wisconsin. 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.

The following individuals will have access to your information from the visit:

- Interviewers from University of Michigan and the authorized research team
- Authorities from Teachers College, including the Institutional Review Board and the Office for Human Research Protection

### Compensation

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You will receive a pre-payment of \$50 as a token of appreciation for participating in the survey. In addition, you will receive another \$50 (for a total of \$100) once you have completed the visit. There are no costs to you for taking part in this study.

### What will happen to the information we collect about you after the study is over?

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A description of this study will be posted on a public website, <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.

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**Who to Contact**

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If you have any questions or concerns about the study, you may contact principal investigator: Kimberly Noble, kgn2106@tc.columbia.edu, (212) 678-3486 or the project director: Lauren Meyer, bfystudy@gmail.com, (608) 291-7359.

**If you have questions or concerns about your rights as a participant:**

There is a group of people, called an Institutional Review Board, organized to protect the rights and welfare of people involved in research. Contact the Teachers College Institutional Review Board:

525 W 120th St, New York, NY 10027  
Telephone: (212) 678-3000  
Email: irb@tc.edu

**If you have any concerns with the University of Michigan interviewers:**

Please contact the University of Michigan, Health Sciences and Behavioral Sciences Institutional Review Board:

2800 Plymouth Road, Building 520, Rm 1169  
Ann Arbor, MI 48109-2800  
Phone: (866) 936-0933  
Email: irbhsbs@umich.edu

**Statement of Consent**

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I have reviewed the consent form including the purpose, procedures, risks, benefits, and alternatives with the interviewer. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study. 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**

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*Parent/Guardian*

Print Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

*Interviewer*

Print Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_