

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

Participation Duration: Four Years
Anticipated Number of Subjects: 1,000
Study Sponsor(s): National Institute of Child Health and Human Development, private 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 role of family experiences on young children's development. Both your and your child's participation in this study is voluntary. The research was intended to last 3 years but for your safety during the Covid-19 pandemic we have postponed some of the study activities to this 4th birthday university visit. 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 are minimal: the primary risks are unlikely disclosure of personal information and possible mild irritation from the EEG cap. If at any time you or your child wish to take a break, 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, 4th Birthday Visit

You have agreed to participate in the research study called Baby's First Years. We want to understand the role of experience on young children's development. **Your decision to participate in the 4th birthday visit will not affect the 4MyBaby card 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.**

The things we will ask you to do during this 2.5 – 3-hour visit

You will have the opportunity to...

- **Take a survey:** answer questions about you, your family, household income/finances; how you have been feeling lately; your romantic relationships; and the last year of your child's life
- **Complete an iPad activity:** a short game to measure attention and sorting

Your child will have the opportunity to...

- **Play a few iPad games and other games:** these activities will measure your child's developing skills. In order to use one of the games we will be playing with your child, non-personally identifiable information such as birth month and year, and gender will be shared with the operator of the app
- **Have an EEG measurement:** during this measurement, your child will wear a child-friendly cap with sensors that can view and record brain activity

Both you and your child will have the opportunity to...

- **Play together:** we will observe and videotape you and your child participating in some activities, with an optional

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additional recording device that will provide information on your child's everyday use of language

- **Donate saliva:** by swabbing the inside of the cheek and gums with a cotton swab, to help us better understand how life experiences show themselves in the body
- **Measure your height and weight**

You can skip any parts of the visit in which you do not want to participate or 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.

If at any time you or your child would like to stop or take a break (e.g. a break for eating or rest) you are free to do so.

We may contact you for future waves of data collection. You have the right to decline to participate at any time.

Risks and Burdens

Risks of participating in this research study to you or your child are minimal.

General risks: Although rare, one 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.

Additionally, you may find some of the questions asked to be too personal, embarrassing or sensitive. You may skip any questions that you do not wish to answer.

EEG and saliva donation risks: The risks associated with using the EEG device with children are minimal and may include some discomfort and mild skin irritation or redness. Risks involved with saliva collection may include mild discomfort. We use certified medical grade equipment which has been safely utilized with children.

Audio/Video recording risks: If you consent to be audio/video recorded or photographed in today's research session there is a potential risk of a loss of confidentiality in your research participation. The research team maintains strict data privacy standards to ensure your personal details and responses are de-identified. Additionally, you may withdraw permission to audio/video record or photograph at any time.

COVID-19 risks: There are inherent risks with in-person research due to the COVID-19 pandemic. Person-to-person exposure is the most frequent route of transmission for infectious viruses and occurs via direct inhalation of repository aerosol during close contact. Infectious diseases are transmitted from person to person by direct or indirect contact. Certain types of viruses, bacteria, parasites, and fungi can all cause infectious disease. Please use caution when traveling in public and follow public health guidelines, such as wearing masks in public and avoiding crowds. Please stay informed about public health recommendations and guidelines regarding COVID-19, such as those issued by the Centers for Disease Control (CDC.gov) and local government guidelines and directives. Some data collection may be conducted remotely via phone.

You are free to stop, skip, or take a break from any part of the research session at any time.

Benefits: There are no direct benefits from participating in this research study. This study may be helpful in understanding

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the factors that affect how children learn and grow.

Confidentiality

Researchers will keep all of your personal data private and secure. Only the study team and members of the Teachers College Institutional Review Board (IRB) may review identifiable data that you provide as part of this study. Otherwise, all information obtained from your participation in this study will be held strictly confidential and will be disclosed only with your permission or as required by U.S. or State law.

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.
 - **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.

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 deidentified information collected in this study may be used for future research studies and will be shared, without your name or any other identifying data attached, with a bank of data maintained at the University of Michigan. This bank is called the Inter-University Consortium for Political and Social Research (ICPSR). The data in this bank can be used by researchers at other institutions besides this one, but the data you have provided can never be traced back to you.

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.

After completing the visit, the information that you provide will be transferred to a secure storage platform at Teachers College, Columbia University and 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.

Saliva: Saliva samples will be mailed without any identifying information to a lab for chemical analysis, and then destroyed. Biospecimens, like saliva, that are collected as part of this study **will not** be used for commercial profit, and analysis **will not** include whole genome sequencing. Biospecimens will be destroyed once they are processed for this study, and **will not** be used in future research studies.

Video and Audio Recording

The purpose of the video- and audio-recorded playtime activity is to understand the different ways in which mothers interact with their babies and the kinds of language that babies are using. The digital audio and video files are stored on a password protected laptop, and will be handled in the same way as the other identifiable information collected in this study (see the "Confidentiality" section for more information). No information that can identify you will be posted publicly. The audio and video files will be stored indefinitely, but you can request for them to be deleted at any time.

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In addition to the playtime activity, we may request for parts of the visit to be recorded for quality control purposes only. If you do not wish to be recorded, you may opt out.

Compensation

For your participation in the research session today you will receive payment and a small toy as a gift for your child. Your compensation is not contingent on completing the study.

- \$200: For the in-person visit
- +\$10: For keeping the originally scheduled appointment

In some limited circumstances, the visit will be split and the survey will be offered via phone in advance of the university visit:

- \$100: For the survey (when completed via phone)
- \$150: For the in-person visit (when following a phone survey)
- +\$10: For keeping the originally scheduled in-person appointment

Transportation

The study team will arrange round-trip car services for your transportation to the university office for your visit.

If you decline a lab-provided car service, you will be paid if you travel on your own. Payment for travel is dependent upon mileage distance (round trip) from your home to the study site as follows: \$25 for 1-40 miles round trip, \$50 for 41-80 miles round trip, \$75 for 81-120 miles round trip, \$100 for 121-160 miles round trip. If your start and end points are different, that is okay; we pay for the total miles driven. We will help you calculating the estimated drive. The rates are above the current IRS mileage reimbursement rate of 58.5 cents per mile. If you live farther than 80 miles away, we will make individual arrangements with you.

Who to Contact

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 at:

525 W 120th St, New York, NY 10027

Telephone: (212) 678-3000

Email: irb@tc.edu

Statement of Consent

I have reviewed the consent form 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 agreeing to continue, I am agreeing to take part in this research study and to be contacted for future study opportunities. 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

Parent/Guardian

Print Name _____ Signature _____ Date _____

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Researcher

Print Name _____ Signature _____ Date _____