

Comprehensive Early Childhood Parenting Supports and Children's Health and  
Development

NCT04226053

12/15/2022

**42M HOME VISIT: CONSENT FORM****Columbia Study of Mothers and Babies****Columbia University****PI: Christopher Wimer****Protocol: AAAR1340**

What is the goal of this research?	This visit is part of the Columbia Study of Mothers and Babies. This is a research study trying to better understand the circumstances of mothers and babies in New York City and to learn about the effects of programs aimed to provide supports to new parents in NYC. This consent form is for participation in the study's home visit for yourself and your child.
What is involved in the home visit?	<p>The first part of the visit includes the following activities:</p> <ol style="list-style-type: none"> <li>1) A computer-based game with the child using a touch-screen laptop (EF Touch) [about 20 minutes]</li> <li>2) A vocabulary game with the child using a picture cue book (ROWPVT-4) [about 20 minutes]</li> <li>3) A follow-up survey with the parent [about 20 minutes]</li> </ol> <p>The second part is an interactive session with you and your child. We will ask you to play with your child for 10 minutes with a set of toys provided to you, and this play will be video-recorded. You do not need to change anything you do with your child.</p> <p>*If you prefer not to be recorded, you can skip this part of the visit.</p> <p>We will also talk about a request to access information about your child from the New York City Department of Education &amp; the Administration for Children's Services.</p>
Is participation my choice?	Yes, the study is voluntary and you may withdraw at any time. If you want to skip any of the activities included in this visit, just let us know and we will go on to the next activity.
How will my information be protected?	We will keep all electronic information on encrypted computers with passwords. Only authorized staff and researchers have

	<p>access to these files. All paper records will be kept in locked cabinets in a locked room.</p> <p>When we finish the video recording, we will lock up the memory chip with your recording. On campus, your recording will be kept in password-protected computer files and will be marked with a special code number, not your name. Video recordings will be destroyed upon completion of the study.</p> <p>The information you provide will only be used for research purposes. No research report will use your name or describe you or your child in a way that would allow you to be identified.</p> <p>The Columbia University Human Research Protection Office and the federal Office of Human Research Protections may have access to the collected data to ensure that the confidentiality and rights of study subjects are maintained.</p>
Is all my information kept confidential?	<p>There are some things that you might tell us that we CANNOT promise to keep confidential.</p> <p>If you give us information which suggests that your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.</p> <p>Your participation in this research study will be documented in your electronic medical record. This record can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and New York-Presbyterian Hospital and its affiliated institutions, because these institutions share the electronic medical system. Study monitors and others who provide oversight of the study may also need to access this record.</p>
What are the risks and benefits?	<p>There are no known risks or benefits associated with your participation in the visit. However, if you become upset during or after the visit, we can give you a service support referral from our online resource guide.</p>
If I consent to the videotaping, can I see the video recording afterwards?	<p>Unfortunately, you will not be able to view the video. Only study staff will have access to the video which again is only for analysis purposes of the research team.</p>

<p>Will I receive compensation for my time?</p>	<p>You will receive \$20.00 for each completed activity included in the first part of the visit: the vocabulary game, computer games and the follow-up survey, a total of up to \$60.00 for completing all three activities.</p> <p>You will receive an additional \$20.00 for participating in the second part – the videotaped play session, a total of <b>\$80.00</b> if you participate in <u>both</u> the first &amp; second parts.</p> <p><b>**Should you opt out and choose not to participate in this visit, compensation will not be offered.</b></p>
<p>What if I have questions?</p>	<p>If you have questions about the study, you can contact the Principal Investigator, Dr. Christopher Wimer, at (phone) 212-854-0245; (email) <a href="mailto:cw2727@columbia.edu">cw2727@columbia.edu</a>.</p> <p>If you have questions about your rights and responsibilities as a research participant, you can contact the <b>Columbia University Human Research Protection Office</b> at: (phone) 212-305-5883; (email) <a href="mailto:irboffice@columbia.edu">irboffice@columbia.edu</a></p> <p>The protocol number for this study is AAAR1340</p>

**Consent for Part 1:** I have read the consent form and understand this research study, including the purpose, procedures, risks, and benefits. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am confirming that I am at least 18 years of age, and I am agreeing to take part in this research study. I understand that I can also stop participating in the study at any time. I am not 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. By signing, I am also confirming that I am the parent or legal guardian of the child whose name appears below, and that I give permission for this child to participate in the study.

Child's Name \_\_\_\_\_

Study Participant Signature \_\_\_\_\_ Date \_\_\_\_\_

Study Participant Print Name \_\_\_\_\_

**Staff Obtaining Consent**

Staff Signature \_\_\_\_\_ Date \_\_\_\_\_

Staff Print Name \_\_\_\_\_

**Consent for Part 2:** I agree to have my image and voice recorded for the Home Visit portion of this study. This video recording will show me and my child playing together with a set of toys provided to me. I understand the recording will be marked with a special code number, not my name. Videos will not be sold. They will not be used for commercial purposes. The video-recording procedures, risks, and benefits have been explained to me. I know I am free to ask any questions. I understand it is my choice. I understand my information will be kept private, to the extent permitted by law, unless there is a concern that myself or someone else may be harmed.

Study Participant Signature \_\_\_\_\_ Date \_\_\_\_\_

Study Participant Print Name \_\_\_\_\_

**Staff Obtaining Consent**

Staff Signature \_\_\_\_\_ Date \_\_\_\_\_

Staff Print Name \_\_\_\_\_

PARENT PERMISSION BOOKLET  
42M HOME VISIT: CONSENT FORM

Columbia Study of Mothers and Babies  
Columbia University

PI: Christopher Wimer  
Protocol: AAAR1340

### **Request for Consent to Access Your Child's DOE Records & ACS Records**

Thank you for being part of the Columbia Study of Mothers and Babies – 42M Home Visit!

As part of this study, the Columbia University research team is asking your consent to access data about your child from the Department of Education, & data about you and/or your child from the Administration for Children's Services (ACS)/Child Protective Services (CPS)/Statewide Central Register of Child Abuse and Maltreatment (SCR).

With your consent, the Columbia team would link your/your child's records to the surveys you have completed with us and any other information you provide on this form. The study's goal is to understand the circumstances of mothers and babies in New York City and to learn about the effects of programs aimed to provide supports to new parents in NYC.

This booklet will help you decide if you want to share this information with the Columbia Study of Mothers and Babies. You do not have to consent to anything you don't want to. You will receive a copy of this booklet for your records.

You will not receive any direct benefit from this study. Your child will not receive any direct benefit from this study. It is very unlikely this study could pose any unknown risks.

Giving consent is your choice. If you do not give consent for Columbia University to access private data, there will be no effect on your child.

If you have any questions about the research or your participation in this study, you may contact the Principal Investigator (PI).

Dr. Christopher Wimer  
[cw2727@columbia.edu](mailto:cw2727@columbia.edu)  
(212) 854-0245

If you have questions about your rights as a study participant, you may contact the Columbia University Institutional Review Board.

[irboffice@columbia.edu](mailto:irboffice@columbia.edu)  
(212) 305-5883

The protocol number is AAAR1340

## Part 1. What Your Child's Participation Would Mean

If you agree to share private information from the DOE &/or ACS/CPS/SCR, we will send along information about you and/or your child. This information will include your child's name, date of birth, and other personal information. It will be used to match you and/or your child with their records.

The DOE and ACS/CPS/SCR will use this information to find your/your child's records. They will remove your/your child's name and other identifying information except for a unique ID number. These records will then be sent to the Columbia team. Using the unique ID, we will link the records to the other information we have about you and/or your child.

### What information about my child will be sent to the DOE & ACS?

In New York City there are many children with the same birthday. There are also many children with the same or similar names. For this reason, we will send as much information as we have to be sure we get the right data for you and/or your child.

The information we will send, if we have it, will include:

- ☐ your child's legal name (first, middle, last)
- ☐ your child's date of birth (month/day/year)
- ☐ the birth mother's name at time of birth (first, middle, last)
- ☐ the birth mother's date of birth (month/day/year)
- ☐ the birth father's name (first, middle, last)
- ☐ your child's ethnicity
- ☐ your child's gender

### How long will this part of the study last?

Our goal is to learn about the effects of programs aimed to provide supports to new parents in NYC. We hope to request DOE records for children in the study all the way through high school – until they graduate or reach age 18, and we will collect ACS/CPS/SCR data through 2023. After that, data from the study will be securely stored at Columbia University so researchers can continue to learn from it.

## Part 2. Your Rights, Our Responsibilities

This section describes how data about your and/or your child will be protected. It refers to data from prior surveys and DOE and ACS/CPS/SCR records. We will tell you more about this data in the next section.

### Your and your child's rights as study participants

Participation in this study is your choice. You may refuse to participate or stop your/your child's participation at any time without penalty.

### Confidentiality of information you and your child provide to the research team

We take the privacy of your family seriously. If you let us access your/your child's records, this data would be linked to the data we collected as part of this study. Your and/or your child's records would be linked to this data using a unique study ID. It would not be linked using your name nor your child's.

None of your and/or your child's records will be shared with anyone outside the research team. Reports written about study will not identify you or your child. Reports will not include other information that

could identify you or your child in any way. The Columbia University Human Research Protection Office and the U.S. Office of Human Research Protections may have access to the data. This is to ensure the privacy and rights of study participants.

**How information is stored**

We will keep all electronic information on protected computers with passwords. Only authorized staff and researchers have access to these files. All paper records will be kept in locked cabinets in a locked room. Your child's DOE records and/or your/your child's ACS/CPS/SCR records will be identified only by a unique study ID.

**Risks and Benefits**

You and your child will not receive any direct benefits from this study. The data collected from this study will help us learn about the health, education, and service use of NYC children. This information may help improve policies in our city. There is a very small risk of the information being seen outside of the study team in the unlikely event of a data breach.

**Payments**

There is no payment for allowing access to your child's school records or your/your child's ACS/CPS/SCR records.

**Withdrawal**

If you change your mind at any point and decide you want to withdraw from this part of the study, the Columbia Study of Mothers and Babies on behalf of Columbia University would stop requesting your child's records from the Department of Education or your/your child's records from the Administration for Children's Services (ACS)/ Child Protective Services (CPS)/ Statewide Central Register of Child Abuse and Maltreatment (SCR). If you decide you want to withdraw, contact the PI, Dr. Christopher Wimer, at (phone) 212-854-0245; (email) cw2727@columbia.edu.



<i>What Type of Consent</i>	<i>What kinds of Information</i>	<i>Consent: YES/NO</i>
<p><b>Consent to Match to Department of Education Records</b></p> <p>Your family is participating in the Columbia Study of Mothers and Babies. As part of this study, Columbia University is requesting your consent to access identifiable student data from the New York City Department of Education.</p> <p>This will include information on your child's school attendance and academic level and track. It also will include test scores for all school years from prekindergarten to the time your child leaves high school.</p> <p>The study's goal is to learn about the effects of programs aimed to provide supports to new parents in NYC. The information collected will be used only for purposes of the study. None of your child's school records will be shared with anyone outside of the study team.</p> <p>*Neither you nor your child will receive any direct benefits from this study. It is very unlikely this study could pose any unknown risks.</p> <p>*Consent is completely voluntary. If you do not provide consent for Columbia University to access student level data, there will be no effect on your child's participation in the New York City public schools.</p>	<p><b>Records that may be disclosed:</b></p> <ul style="list-style-type: none"> <li>▪ Student grade level</li> <li>▪ Academic grade level and track</li> <li>▪ Student IEP status and disability classification English Language Learner status</li> <li>▪ Number of days absent</li> <li>▪ Grade level, raw score, and scale score of Math and ELA exams</li> <li>▪ Subject of Advanced Placement exams taken</li> <li>▪ Type of high school diploma (Local, Regents, or Advance Regents)</li> <li>▪ Whether the student dropped out or transferred to a state approved GED program</li> <li>▪ Body mass index and percentile</li> </ul>	<p><b>If you CONSENT, you are understanding &amp; acknowledging the following:</b></p> <ul style="list-style-type: none"> <li>· I have read and understand Parts 1 and 2 of this form. I have had the chance to ask questions about the study.</li> <li>· My/my child's participation in this part of the study is my choice. I may refuse to take part or stop at any time. If I stop, it will not affect benefits or services for anyone in my family.</li> <li>· Any study records that identify my child will not be voluntarily released or revealed without my consent, unless someone may be in danger or the law requires their release.</li> <li>· The research staff will not share my child's name or anything that identifies him/her with anyone outside the NYC Department of Education.</li> <li>· I am 18 years or older. I am the parent or legal guardian of my child. I give my consent for the research team to link to my child's education records.</li> </ul> <p>I give my permission to access my child's education records. (Please initial next to your answer.)</p> <p>YES: _____ NO: _____</p> <p>If YES, please fill out and sign the section below.</p> <p>Child's Legal Name: _____</p> <p>Child's Birthdate: _____</p> <p>Parent / Guardian Name: _____</p> <p>Parent / Guardian Signature: _____</p>

<b><i>What Type of Consent</i></b>	<b><i>What kinds of Information</i></b>	<b><i>Consent: YES/NO</i></b>
<p><b>Consent to Match to Child Protective Services (CPS) &amp; Administration for Children's Services (ACS) Records</b></p> <p>Your family is participating in the Columbia Study of Mothers and Babies. As part of this study, Columbia University is requesting your consent to data about you and your child from the Statewide Central Register of Child Abuse and Maltreatment (SCR).</p> <p>This will include information about all SCR reports involving you or your child and their dates, as well as all placements of the child into foster care and the start date. We would like access to this information from 2016 through 2023.</p> <p>The study 's goal is to learn about the effects of programs aimed to provide supports to new parents in NYC. The information collected will be used only for purposes of the study. None of your or your child's records will be shared with anyone outside of the study team.</p> <p>* Neither you nor your child will receive any direct benefits from this study. It is very unlikely this study could pose any unknown risks.</p> <p>** Consent is completely voluntary. If you do not provide consent for Columbia University to this data, there will be no effect on your participation in the study.</p> <p>*** The research team will not have access to the outcome or determination of any investigation.</p>	<p><b>Records that may be disclosed:</b></p> <ul style="list-style-type: none"> <li>▪ All SCR reports involving you OR your child &amp; their dates for the years 2016 through 2023.</li> <li>▪ All placements of the child into foster care &amp; the start date for the years 2016 through 2023.</li> </ul>	<p><b>If you CONSENT, you are understanding &amp; acknowledging the following:</b></p> <ul style="list-style-type: none"> <li>· I have read and understand this consent form. I have had the chance to ask questions about the study.</li> <li>· My/my child's participation in this part of the study is my choice. I may refuse to take part or stop at any time. If I stop, it will not affect benefits or services for anyone in my family.</li> <li>· Any study records that identify myself or my child will not be voluntarily released or revealed without my consent, unless someone may be in danger or the law requires their release.</li> <li>· The research staff will not share my or my child's name or anything that identifies us with anyone outside of ACS, CPS, &amp; SCR.</li> <li>· I am 18 years or older. I am the parent or legal guardian of my child. I give my consent for the research team to link to my/my child's SCR records.</li> </ul> <p>I give my permission to access my/my child's SCR records. (Please initial next to your answer.)</p> <p>YES: _____ NO: _____</p> <p>If YES, please fill out and sign the section below.</p> <p>Child's Legal Name: _____</p> <p>Child's Birthdate: _____</p> <p>Parent / Guardian Name: _____</p> <p>Parent / Guardian Signature: _____</p>

If you have given the Columbia University study team permission to access your child's school records or your/your child's SCR records, please read below.

Many children in New York City have the same birthday and may have the same or similar names. Providing us with more information helps us make sure we have the correct records for your child.

You can help by filling out any of the information below that you know and feel comfortable sharing.

**Primary Match Criteria:**

Child's legal name (first, middle, last):

---

Child's date of birth (month/day/year):

---

Birth mother's name (first, middle, last):

---

Birth mother's date of birth (month/day/year):

---

Father's name (first, middle, last):

---

**Secondary Match Criteria:**

Child's Ethnicity:

---

Child's Gender:

---

Thank you for your time and participation!