NYU Langone MEDICAL CENTER

Research Subject Informed Consent Form

Title of Study:	Caregiver-Child Interaction and Health Behaviors
Principal Investigator:	Dr. Richard E. Heyman Cariology and Comprehensive Care NYU College of Dentistry 137 E. 25th St, 6th Floor New York, NY 10010 212-998-9984
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

You and your child are being asked to participate because we are interested in typical caregiver-child interactions and health behaviors. In particular, we are interested in different ways that caregivers react to and understand their young children’s behavior, and their health behaviors.

3. How long will I be in the study? How many other people will be in the study?

If you choose to participate, you and your child will be in the study for approximately 4 and a half to 5 and a half hours total over 2 visits. The first visit will be approximately 2 and a half hours to 3 hours long.

The second visit will be approximately 2 to 2 and a half hours long. You will not have to participate in any follow up activities after the second visit.

A total of 200 caregivers and 200 children (400 subjects total) will participate in this study.

4. What will I be asked to do in the study?

If you decide to participate in this study, you and your child will come visit our laboratory twice at times that are convenient for you. The first visit will take 2-2.5 hours and the second visit will take 1.5-2 hours, so we will ask you to schedule them at times when your child will be well-rested and fed prior to arrival. Here is a list of activities that we will ask you to participate in. These activities will be video-recorded and recordings will be kept digitally on a secure password-protected server. A separate consent form for the video-recording will be provided and you must consent to the video-recording if you wish to participate in this study. Video-recordings will be assigned a random subject ID number.

- Upon arrival at our laboratory during both visits, we will explain the tasks to you and we will set you and your child up with our machine that allows us to measure heart rate and skin moisture. This means we will place nine sensors on your and your child's bodies. These sensors will be placed on the collar bones, the lower left rib cage, the upper and mid-chest, the upper and mid-back, and the palm of your and your child's non-dominant hand. You and your child will still be able to move freely around the room.

- Next, we will either

    - Conduct a short discussion where we will discuss your responses to your child's behavior or the intentions behind your child's behavior. A quarter of the research subjects in this study will complete a task where their responses to their child's behaviors are discussed and another quarter of the subjects will complete a task where the reasons for their child's behavior are discussed. Which type of discussion you have will be "randomly assigned", which means that a computer will generate this decision before you arrive for your visit.

    - Or have you complete a short computerized activity where you will look at a series of images and descriptions or will be asked to rate a series of images with facial expressions. A quarter of the research subjects in this study will complete a computerized activity where they will look at a series of images and descriptions and another quarter of the subjects will complete a computerized activity where they will rate a series of images with facial expressions. Which type of activity you have will be "randomly assigned", which means that a computer will generate this decision before you arrive for your visit.

- After, we will have you and your child complete a series of tasks that are the sorts of activities you might encounter in daily life. In the first task we will have you direct your child to clean up toys. In the second task we will have your child play with some toys while you are occupied on your phone. In the third task we will give you questionnaires to complete while your child waits on a mat. All three of these tasks will take 25-30 minutes.

- After this task, we will either:
    - Allow you to have a break with your child. We will provide toys, drinks and snacks during the break.
    - Or have you complete a task where you will rate what you felt and thought during your interaction with your child while watching a video of your interaction
- We will then ask you to brush your child's teeth with a toothbrush that we provide, as you normally would.
- At the end of these tasks we will provide you with the opportunity to discuss the visit, your child's behaviors, and any other questions or concerns you may have. We will not ask you to participate in any additional visits or questionnaires after your second visit.

5. What are the possible risks or discomforts?

Risk of Study

Some of the questionnaires that we will ask you about are sensitive in nature. You or your child may also experience some distress in reaction to the tasks. This distress should be mild and fleeting, as these tasks are similar to real-life circumstances that you may both experience where your child has to wait for you while you are occupied, or is asked to put toys away. You have the right to refuse to answer any question or refuse to participate in any task. In addition, all research may involve additional risks that are currently unforeseeable.

Other Risks

As in any study, there is a risk of your confidentiality being breached. You have the right for your participation in this study to be kept confidential. We are conducting heart rate and skin moisture assessments, which mean that we are collecting measures of your and your child's physiology. We will keep all information in locked file cabinets and on password-protected computers with secure servers. All of the information you give us is completely confidential. Your names will go only on the consent forms and payment receipts. Those documents will be kept completely separate from your data. Your names will not go on any of the questionnaires you are going to fill out. All the information will all be coded with a random number. All the information will all be coded with a random number. That number will only be attached to your name in a separate, password-protected, linking database that will be kept completely secure. That way, we will not be able to link your name, address, or phone number to your data, except by using this secure database. Only trained research staff will have access to your data, except for specific representatives as outlined below, and only trained research staff will be able to access the linking database.

Certificate of Confidentiality

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 or documents 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 or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse , or if we determine that you are in danger of harming yourself or others.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

There are no direct benefits to participating in this research study. Some caregivers find that thinking about their caregiving and discussing it with a trained researcher may help them to understand themselves or their child better. In addition, you are helping us to understand caregiver-child interactions and health behaviors in families with young children.

8. What other choices do I have if I do not participate?

The alternative to participating in this study is not participating. You will not be penalized in any way for not participating in the research.

9. Will I be paid for being in this study?

You will be paid $200 total - $60 for the first visit and $140 for the second visit - to compensate you for your time during this research study. If you keep your initial appointment for your first visit, you will also be paid a $20 total cash bonus. If you complete your second visit within 2 weeks of your first visit, you will be paid another $20 total cash bonus. If you refer another family to our study, you will receive a $20 total bonus in the form of an e-gift card. Additionally, you will receive a 2-ride MetroCard (per visit) to compensate you for your travel to our lab. If you choose to leave or withdraw early from the study for any reason before finishing the entire study, you will be paid on a pro-rated basis for your time.

10. Will I have to pay for anything?

You will not have to pay anything to participate in this research study.

11. What happens if I am injured from being in the study?

We do not anticipate that any study procedures should result in injury to you or your child. For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The contact information for the principal

investigator, Dr. Richard Heyman, can be found at the top of page 1 of this consent form. If such a complication were to arise, the study investigator will assist you in obtaining appropriate treatment but this study does not provide financial assistance for related costs. Likewise, there are no plans for the NYU School of Medicine or Medical Center to pay you or give you other compensation for an injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the study before it ends?

Your participation in this study will end at the end of the second visit. Your participation is entirely voluntary and you can withdraw at any time without any penalty. If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

13. How will my information be protected?

NYU Langone Medical Center, which includes NYU Hospitals Center and NYU School of Medicine, is committed to protecting the privacy and confidentiality of your health information. You have the right not to give us this permission, in which case you will not be able to participate in this study. If you do not give this permission, your treatment outside of this study, payment for your health care, and your health care benefits will not be affected. We will not be sharing any of your health information with researchers outside of NYU. Your responses will be kept confidential with the following exception: the researcher is required by law to report to the appropriate authorities, suspicion of harm to yourself, to children, or to others.

Why is my information being used?
Your health information will be used by the research team and others involved in the study to conduct and oversee the study.

Who may use and share information about me?
The following individuals may use, share or receive your information for this research study:

- The Principal Investigator, study coordinators, other members of the research team, and personnel responsible for the support or oversight of the study.
- Governmental agencies responsible for research oversight (e.g., the National Institute of Health).

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time. If you withdraw your permission, we will not be able to take back information that has already been used. To withdraw your permission, send a written notice to the principal investigator for the study, Dr. Richard Heyman, noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

14. Optional permission for future use

Will I be re-contacted for future research?

We would also like your permission for our research staff to contact you regarding your interest in participating in other current and/or future research studies. These studies may include laboratory and/or home visits. They may also include online, phone, and/or paper questionnaires. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to be contacted for other current and/or future research studies.

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Subject Initials

NYULMC would also like to store, use, and share your health information from this study in research databases or registries for future research conducted by NYULMC or its research partners. To give this additional permission, check the box below and write your initials where indicated. You may still participate in this study even if you do not give us this additional permission.

NYULMC will continue to protect the confidentiality and privacy of this information as required by law and our institutional polices. If you give this additional permission, you will continue to have the rights described in this form. You have the right to take back this additional permission at any time.

☐ Checking this box indicates my permission to store, use, and share my health information from this study in research databases or registries for future research conducted by NYULMC or its research partners.

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Subject Initials

15. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

16. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator, Dr. Richard Heyman, listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Signature of Caregiver/Guardian for Child

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Name of Caregiver (Print)	Signature of Caregiver	Date

Name of Child (Print)