Cover Letter for Document

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NYU Langone MEDICAL CENTER

Research Subject Informed Consent Form

Title of Study:	Integrated model for promoting parenting and early school readiness in pediatrics
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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?

The purpose of this study is to determine whether programs in pediatric clinics and in children’s homes can help children develop the skills needed to succeed in school.

You are being asked to participate in this study because you have a healthy newborn baby AND plan to receive your child’s pediatric care at Bellevue’s pediatric clinic.

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

This study begins when your child is a newborn (between 1 day and 2 months old) and will continue until your child has completed elementary school.

About 1200 people will be in this study. Of these, 600 are taking part in this study at Bellevue Hospital Center (in NYC), and 600 are taking part at Children's Hospital of Pittsburgh (in Pittsburgh, PA).

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

This study involves three components: a. Programs for parents and children, b. Interviews and Observations, and c. Health/Education. Each component is described below.

a. Programs for parents and children:

For the part of this study involving programs for parents and children, you will be put into one of three groups. You will learn which group you are in when you meet with us next at your child's pediatric appointment.

This study alternates between two phases: VIP Phase and RCT Phase.

- All families who join the study while it is in VIP phase will be put into Group 1.
- All families who join the study while it is in RCT Phase will be *assigned by chance* to either Group 2 (50% of families) or Group 3 (50% of families). This random assignment has nothing to do with anything about you, your family, or your child; instead, the choice is made in a way similar to flipping a coin.

Here are some details about the three groups:

Group 1: Video Interaction Project Group

If you are in this group, you will take part in a program called the 'Video Interaction Project' (VIP). For this program, a Parent-Child Specialist will meet with you and your child each time that you go to your child's doctor for his or her well-child visits. The Child Development Specialist will talk to you about ways to help your child and will videotape you and your child playing together. At each of these sessions, you will receive a copy of this video as well as a parenting pamphlet, and a toy or a book for your child.

Group 2: Video Interaction Project / Family Check Up Group

If you are in this group, you will take part in a program called the 'Video Interaction Project'. For this program, a Child Development Specialist will meet with you and your child each time that you go to your child's doctor for his or her well-child visits. The Child Development Specialist will talk to you about ways to help your child learn language and other skills and will videotape you and your child playing together. At each of these sessions, you will receive a copy of this video as well as a parenting pamphlet, and a toy or a book for your child.

Some families in this group will also take part in a program called 'Family Check Up', in which a parent-child coach will visit you at your home to provide additional guidance and support regarding your child's development and behavior. These visits will take place three or more times and will include additional videotaping of you and your child.

Group 3: Control Group

Families in this group will not receive additional parent-child programs but will continue to receive all regular pediatric care.

b. Interviews and observations:

No matter which group you are assigned to, you will be asked to complete a set of interviews and observations. Each interview/observation will last around 2 hours and will be conducted at in-person meetings, by phone, or in the home.

There are 1 or 2 interviews/observations this year and 1 or 2 more next year. You may also be asked to complete up to one interview/observation per year as your child gets older.

For these interviews/observations, we will ask you questions about your child, your family, your home and any experiences that you have had with our programs and the health care system. For observations that take place in person, we will audio/video record you and/or your child and have you and your child participate in tests of development, reading, and other topics. Some topics that will be covered include:

- Your experience of being a parent
- Family / household characteristics, resources and challenges
- Feelings that you might have of depression or stress
- Plans and hopes for you and your child
- Your child's health status
- Routines and activities you do with your child such as feeding, sleeping, playing and reading
- Your child's language, cognitive and social-emotional development
- Your experience with the health care system, including our programs

c. Health/Education:

A main focus of this project is to study your child's development and success in school. In order to best do this, we will review your child's medical record to obtain information regarding factors that might affect his or her development, including prenatal and medical complications, birth history, blood count, lead exposure, growth, nutritional status, attendance in well child care, and medical diagnoses.

If your child participates in Early Intervention (EI), we will ask the New York City EI program to share any information about testing or services that may have taken place, and we will also share the results of our observations with EI. Also, when your child is older we will ask the NYC Department of Education or other educational programs that your child attends about your child's development, behavior and educational progress.

For participants assigned to Groups 1 or 2, we will also review your records from the Video Interaction Project and/or Family Check Up, including participation in visits. We will review videotapes made of you and your child as part of these programs.

5. What are the possible risks or discomforts?

Risk of Study

No medical procedures will be performed in this study, and we do not expect any risks or discomforts to be associated with participation in the study. Some participants may have unexpected anxiety or distress because of questions that we ask you. If you become upset or do not wish to answer certain questions, you may stop at any time or may choose not to answer those questions. We will also try to reduce any anxiety by explaining what we are doing at each step and by helping you to identify additional services for you and/or your child if we believe that services are needed.

Other Risks

There is a risk in any study, including this one, of loss of confidentiality. However, this risk will be minimized by keeping study records in a secure database on a password-protected server that is only available to program staff.

It is our legal and ethical responsibility to inform authorities if we encounter evidence of child abuse or maltreatment. Child maltreatment is defined as physical or mental injury, sexual abuse or exploitation, negligent treatment, or maltreatment of a child by a guardian, under circumstances that indicate that the child's health or welfare is harmed or threatened.

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, documents, or biospecimens 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, documents, or biospecimens 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, such as child abuse and neglect, or harm to self 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 may be no direct benefit from agreeing to participate in this study. However, your participation will help us understand whether programs in pediatric clinics help children succeed in school. In addition, if any problems are identified, you or your child will be referred for appropriate services.

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

Your decision as to whether or not to take part in this study is completely voluntary, and you are free to choose not to participate. If you decide not to take part in this study it will not affect the care you and your child receive and will not result in any loss of benefits to which you and your child are otherwise entitled.

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

As reimbursement for your time, your family will receive a $50 gift card after participating in the initial assessment/grouping, an additional $50 gift card for every assessment that you complete through age 3, and $60 as either cash or a gift card for each assessment you complete afterwards. If you choose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for the time that you have contributed to the study.

Each time you visit Bellevue Hospital Center specifically to participate in our study, we will also provide you with a MetroCard to cover the cost of round-trip travel for you and your child.

10. Will I have to pay for anything?

There will be no costs to you for being in this research study.

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

As there are no medical procedures in this study, we do not anticipate any possibility of injury resulting from this study. If you think you have been injured as a result of this study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1. For medical emergencies contact 911.

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

This study is expected to end after all participants have completed all assessments and all information has been collected. If you decide to be in the study, you are free to leave the study at any time. Leaving the study will not affect the care you receive at Bellevue Hospital Center. Please note all the data that has been collected on you to the point that you leave the study will remain part of the study.

This study may also be stopped or your participation ended at any time if:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- The study sponsor, the principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

13. How will my information be protected?

Federal law requires NYU School of Medicine to protect the privacy of any health information that identifies you. This law is called the Health Insurance Portability and Accountability Act (HIPAA). We must keep all your personal health information private unless you give us permission to share it. If you decide to consent to be in this research study, you are giving us permission for your health information to be used within NYU School of Medicine and to be shared with others outside NYU School of Medicine as described below. By signing this form, you are giving the research team permission to use your private health information for this study. If you do not want to allow this, you cannot be in this study.

What information about me may be used or shared with others?
Information in your child's research record may be used or shared with others (listed below).

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 at NYU School of Medicine, NYU, and University of Pittsburgh.
- Governmental agencies responsible for research oversight.
- Health care providers who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.

NYU School of Medicine keeps your research records private according to state and federal laws. If your study information is given to others outside of NYU School of Medicine (other than study personnel at NYU and University of Pittsburgh), the information that can identify you will be removed. This will protect your confidential health information. Your research record has a code that we use to identify you. This code will not be given to anyone unless required by law.

Your research records will be stored so as to be unavailable to anyone but study staff. All paper records are stored with a locked door and locked drawer. All computerized records are password protected. Your research record will be kept for at least three years after the study is over. They will be stored in a place that will not allow anyone to see them without permission. Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

Your Privacy Rights

- You have the right not to sign this form allowing us to use and share your health information for research. If you do not sign this form, you cannot take part in this research study. This is because we need to use the health information of everyone who takes part in this research study.
- If you sign this form and allow us to use and share your health information for research, you have the right to withdraw your permission at any time. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form.
- If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. This includes information used or shared to carry out the research study or to be sure the research is safe and of high quality

14. Optional permission for future use

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. _____ 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 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.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this website site at any time.

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

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness

I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date