The Children's Hospital of Philadelphia®
PHILADELPHIA DEPARTMENT OF PUBLIC HEALTH

Informed Consent Form and HIPAA Authorization

Title of Research: Reducing Disparities in Early Intervention Use: The Opening Doors to Early Intervention Study

Version Date: August 8, 2020

Consent Name: Main Study

Investigator's Name: James Guevara MD, MPH Telephone: (215) 590-1130

You and your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff.

Why are you being asked to take part in this study?

You are being asked to take part in this research study because you have a child younger than 30 months old. Your child was recently referred to the Philadelphia Infant and Toddler Early Intervention (EI) Program in Philadelphia County.

What is the purpose of this research study?

The purpose of this research study is to see if a "Family Navigator" is helpful to families who have been referred for EI Services.

How many people will take part?

About 360 parent-child pairs from up to 6 different CHOP primary care clinics will take part in this study.

What is involved in the study?

The study involves answering questions about your experiences with the Early Intervention process. You will also answer questions about yourself and how you read with your child. You will be randomly assigned to the Family Navigator group or the Usual Care group. If you are given a Family Navigator, this person will keep in touch throughout the study. They will call weekly or monthly to help you with the EI process. Your child will have a developmental assessment at the end of the study.

How long will you be in this study?

If you agree to take part, your participation will last for around 12 months and will involve 5 study visits.

What are the study procedures?

Some of the procedures in this study will be repeated several times. The study involves the following tests and procedures.

Early Intervention Records: We would like a copy of your EI records. We will ask you to sign a Release of Information form. This allows EI to send us the records.

Questionnaires/Surveys: At the beginning of the study, we will ask about yourself and how you read with your child. Since one of the measures is interactive, in the event that the first visit must be done remotely (i.e., by phone, email, or video conferencing), you will have the option of either completing this measure by using a video conferencing application or completing the measure in-person at a later date. If you choose to use the video conferencing application, you will not be recorded and you will not need to have your camera on.

For the other 4 study visits, we will ask you to answer questions and fill out forms that ask about your experience with the EI process, as well as questions about yourself, including sensitive questions about early childhood experiences such as possible experiences of witnessing violence, sexual abuse, discrimination, and substance abuse (for example: *Did you feel safe growing up in your neighborhood?, Were you ever in foster care?).* These sensitive questions will only be asked of you once throughout the study. You do not have to answer any questions that make you feel uncomfortable. All of your responses are protected and private. We will provide you with numbers to organizations that you may call if you would like to speak with a professional about any feelings you might have after completing the survey. If emergency medical or other mental health services are required, you are responsible for any cost.

Developmental Assessment: In the 12th month of the study, early childhood assessors will watch your child play with toys to see how they play and what they know.

Follow-up Reminders: We will send you study-related reminders throughout the study. These may be from phone call, text message, or email. We will contact you by your preferred method. If assigned a Family Navigator, they will contact you weekly to monthly by your preferred method.

Family Navigator Communication: If you are assigned a Family Navigator, they will partner with you, the clinicians, and EI representatives and provide ongoing communication. They will contact you on a weekly or monthly basis, whichever you prefer, to help you throughout the EI process. The Family Navigator will also meet with you at the start of the study to go over the results of your child's developmental and/or milestone assessments.

Will I receive the test results?

The research staff will give you information on your child's developmental assessment by telephone or in written form. We will tell you if we have concerns about your child's development. We can talk about results and resources that may be helpful.

Visit Schedule

The table below shows the purpose and length of each study visit.

Study Visits	Purpose	Duration	What will happen?	Where will it be?
Enrollment + First Study Visit **Child is under 30 months old*	Informed consent, screening, randomization, surveys (including about parent engagement)	45 minutes	We will ask you questions and give you forms to fill out.	In person at CHOP Primary Care center near you or another location you prefer, by email, by telephone, or by a video-conferencing platform
Study Visit 2 *3 months after the first study visit*	Surveys about parent engagement, completion of EI referral, eligibility for the start of EI services, and early childhood experiences	20 minutes	We will ask you questions and give you forms to fill out.	In person, by email, or by telephone
Study Visit 3 *6 months after the first study visit*	Surveys about parent engagement, completion of EI referral, eligibility for the start of EI services	20 minutes	We will ask you questions and give you forms to fill out.	In person, by email, or by telephone
Study Visit 4 *9 months after the first study visit*	Surveys about parent engagement, completion of EI referral, eligibility for the start of EI services	20 minutes	We will ask you questions and give you forms to fill out.	In person, by email, or by telephone
Study Visit 5 *12 months after the first study visit*	In person developmental evaluation of the child. Surveys about parent engagement, completion of EI referral, eligibility for the start of EI services	1 hour 15 minutes	We will ask you questions and give you forms to fill out, and an early childhood assessor will watch your child play to see what they know and how they interact with others.	In person at the Center for Human Phenomic Science at CHOP or another location you prefer. Surveys may be

				completed in person, by email, or by telephone.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

While in this study, you are at risk for the following side effects:

Risks associated with Breach of Confidentiality:

As with any study that collects data, there is the possibility of breach of confidentiality. Every precaution will be taken to protect your personal information to ensure confidentiality.

When you enroll, you will be assigned a study identification number. This number will be used on data collection forms and in the database. We will maintain a separate list that links your name to this number for future reference and communication.

Risks associated with completing questionnaires/surveys:

You may feel uneasy about answering some questions that may seem personal. You do not need to answer questions that make you feel uncomfortable. You may stop at any time.

Risks associated with the developmental assessment:

There are no physical risks but you may feel some embarrassment or discomfort.

If the results of the developmental assessment suggest that your child might need further evaluation or care, we will encourage you to talk with your child's primary care provider.

Are there any benefits to taking part in this study?

There will be no direct benefit to you from participating in this study. The knowledge gained from this research may help health care providers and EI staff care for children with developmental delays.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

What choices do you have other than this study?

There are options for you other than this study including:

- Not participating in this study.
- Continuing with the Early Intervention process as usual.
- You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you and your child will be collected. This will include information from medical records, procedures, interviews, the developmental assessment, and EI records that we will get from Philadelphia Infant Toddler Early Intervention in the Department of Behavioral Health and Intellectual Disabilities Services. Information related to your child's medical care at CHOP will go in your child's medical record. Medical records are available to CHOP staff. Staff will view your child's records only when required as part of their job. Staff are required to keep you and your child's information private. Information that could identify you or your child will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Additionally, any information about child abuse or intent to harm yourself or others will be reported to authorities, as required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP
- Members of the Philadelphia Department of Public Health Institutional Review Board
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- The National Institutes of Health (NIH) who is sponsoring this research

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study. Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

A Certificate of Confidentiality (CoC) covers this research. A CoC helps protect your identifiable information.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- **No one can be forced to share your identifiable information for a lawsuit.**
- **Your information can't be used as evidence even if there is a court subpoena.**

If you consent, your information can be shared for:

- **your medical treatment and/or for use by your insurance company;**
- **other purposes not connected with this research.**

The CoC does not prevent some disclosures.

- **The researchers can't refuse requests for information from those funding this research. The National Institutes of Health (NIH) may need information to assess this project.**
- **You can still share information about yourself. You can also freely discuss your involvement in this research.**
- **The researchers must disclose things required by law. This includes suspected child abuse or communicable diseases.**
- **Some information from this study must go in your medical record.**
- **Your information may be shared for other research.**

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator either in writing, or by phone call.

Dr. James Guevara
Children's Hospital of Philadelphia
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34th Street and Civic Center Blvd.
Philadelphia, PA 19104
Telephone: (215) 590-1130

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Additional Information

A Data Safety and Monitoring Board (DSMB) will review all data and safety reports to ensure participant safety.

If you have questions about your rights, please contact the *Research Participant Coordinator* at:

Philadelphia Department of Public Health
Institutional Review Board
phone: 215-685-0869
email: research.participant.DPH@phila.gov

Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

Will there be any additional costs?

If you choose to talk to research staff or your Family Navigator by text, standard text messaging rates may apply.

Will you be paid for taking part in this study?

You will be paid after you complete each visit to thank you for your time. Payments will be given on pre-paid CHOP-issued debit cards. The makers of the card will not have access to any medical information.

- You will be paid $40 after completing the 1st Study Visit
- You will be paid $20 after completing each of the 2nd, 3rd and 4th Study Visits
- You will be paid $100 after completing the 5th Study Visit

If you are paid with a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

You will be offered the option of arranged transportation to the 5th Study Visit or travel reimbursement:

- If you have a car seat, we may be able to arrange transportation for you and your child. If your travel to CHOP (e.g. car ride) is arranged and paid for by the study team, the agency making the reservations and their representatives will have access to identifiable information.
- If you do not have a car seat, or would like to arrange your own transportation, we can reimburse you for your travel expenses based on mileage. The reimbursement will be given on your pre-paid CHOP-issued debit card.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. James Guevara at 215-590-1130. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

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 Web site at any time.

Consent to be Contacted for Future Research

Please indicate whether you will allow us to contact you in the future for other research studies by putting your initials next to one of the following choices:

_____ (initials) I do not wish to be contacted in the future for any other research studies.

_____ (initials) You may contact me in the future for other research studies.

Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent	Signature of Person Obtaining Consent
	Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part and to allow your child to take part in this research study, and you are legally authorized to consent to your child's participation. You are also agreeing to let CHOP use and share the health information that will be collected for this study, as explained above. If you don't agree to the collection, use, and sharing of health information, you and your child cannot participate in this study. **NOTE:** *A foster parent is not legally authorized to consent for a foster child's participation.*

Consent for Child's Participation

Name of Subject	
Name of Authorized Representative	Relation to subject: ☐ Parent ☐ Legal Guardian
Signature of Authorized Representative	Date

Consent for Parents' participation

Name of Parent	
Signature of Parent	Date