Title: The Opening Doors to Early Intervention Study (ODEI)

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Title:	**Reducing Disparities in Early Intervention Use: The Opening Doors to Early Intervention Study**
Short Title	Opening Doors to Early Intervention (ODEI) Study
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ABBREVIATIONS AND DEFINITIONS OF TERMS

CECPS	Client Engagement in Child Protective Services
EI	Early Intervention
StimQ	Measure of Cognitive Stimulation Provided in the Home
SAHL	Short Assessment of Health Literacy
BSID-III	Bayley Scales of Infant and Toddler Development, Third Edition
PITEI	Philadelphia Infant Toddler Early Intervention
FN	Family Navigator
IFSP	Individualized Family Service Plan
ACE	Adverse Childhood Experiences
CRS	Co-Parenting Relationship Scale
FF	Family Foundations

ABSTRACT

Context:

Developmental delays are frequently encountered among young children but disproportionately affect impoverished minority children leading to disparities in early child development. To promote healthy child development and reduce disparities, the Individuals with Disabilities Education Act (IDEA) mandates early intervention (EI) services be made available to young children with identified delays. However, only half of at-risk children initiate and complete referrals for EI services. Research suggests this may be due to misperceptions about EI services and logistical barriers that impede participation. As a result, many at-risk children do not receive needed services to improve their development early in life. It is unknown what strategies are effective to promote follow through with EI services. Thus, there is a critical need to identify effective strategies to foster initiation and completion of EI services among at-risk children. In the absence of such knowledge, public health agencies lack understanding of effective strategies to assist families with obtaining EI services and may propagate existing health disparities. Our long-term goal is to develop effective strategies to promote child development and reduce disparities through the development of our Opening Doors to Early Intervention Program, a patient navigation intervention designed to facilitate follow through with EI referrals and services. One parent from currently enrolled parent-child dyads in the Main RCT, will be recruited to participate in the sub-study which entails answering questions about safety net program use prior to and during the current COVID-19 pandemic through the completion of a survey. A subset of the sub-study participants will also be asked to participate in an audio-recorded semi-structured telephone interview to identify their perceptions of program assistance and needs. To determine changes in use of services, we will analyze differences in the proportion with past year and current program use to determine changes in demand for individual program services during the COVID-19 pandemic. In a separate sub-study, up to 50experts will be participating in the Delphi consensus process and parents that are enrolled in the Main RCT study will participate in a virtual focus group using a CHOP approved conferencing software, to adapt an evidence based co-parenting program for caregivers who have experienced childhood trauma.

Objectives:

1) To test the effectiveness of the Opening Doors to Early Intervention Program on EI service use and child developmental status among poor minority children residing in an urban community.

2) To develop a measure of engagement and assess whether parent engagement mediates the effects of the Opening Doors to Early Intervention Program.

3) To explore whether the home learning environment, parental health literacy, or poverty moderate the effects of the Opening Doors to Early Intervention Program on child developmental status.

4) To determine changes in use of and need for safety net programs and adjustment to a remote service delivery model for Early Intervention services among low-income families of children with developmental disabilities during the current COVID-19 pandemic in Philadelphia.

5) To adapt an evidence-based co-parenting program for use among caregivers who have experienced significant trauma and chronic stress as a child.

Study Design:

The main study is a prospective, randomized comparative effectiveness trial to study the effects of a novel patient navigation strategy on the use of EI referrals and services and on child developmental outcomes among at-risk urban minority children. For the sub-study, a total of around 128 subjects, one parent from each of the currently enrolled parent-child dyads in the Main RCT, will be recruited to participate in the COVID-rapid response sub-study. A subset of around 50 participants will be enrolled into the sub-study, along with up to 50 experts (in the fields of parenting, childhood trauma, and/or co-parenting) to participate in focus groups and Delphi consensus process.

Setting/Participants:

In the randomized controlled trial, we plan to recruit 4-6 urban practices from CHOP's Pediatric Research Consortium (PeRC) to participate in the study. These practices care for a diverse, complex urban population and have onsite social workers to assist with family crises.

A total of 360 eligible children, 90 children/year, will be recruited from participating practices to achieve a diverse sample of children. Children will be eligible to participate if they are <30 months old, >35 weeks estimated gestational age, reside in Philadelphia, have parents who speak English or Spanish, and have recently been referred to the Philadelphia Infant Toddler Early Intervention Program in Philadelphia County. Children >30 months old will not be eligible, since they are transitioning to Preschool Early Intervention (Part B services) and have little time for retention or completion of the program. In addition, children outside of Philadelphia County will not be eligible, since they would be referred to EI services in a different county. Children will be excluded if they have received EI services in the past two weeks.

The COVID-19 Rapid Response sub-study will recruit around 128 subjects from the Main RCT, one parent from each of the currently enrolled parent-child dyads in the Main RCT. Subjects are eligible if they have participated, or are currently participating, in the Main RCT and have provided permission to be contacted for future studies.

The Childhood Trauma sub-study will recruit up to 50 experts in the fields of parenting, childhood trauma, and/or co-parenting to participate in a modified Delphi consensus process

concerning childhood trauma topics to include into an existing co-parenting primary program used nationally in childbirth educational settings. Then, up to 50 parents of subjects from the Main RCT to participate in a virtual interviews to provide feedback on the adapted co-parenting program.

To summarize, a total of 410 subjects are anticipated between the two subject groups designated for this study. The first group of subjects will include 360 participants for the Main RCT study, and these subjects will be recruited for the COVID-19 sub-study and also for Phase 2 of the Trauma-Informed Co-parenting Sub-study. The second group of subjects (Delphi Consensus group) will include up to 50 experts that will participate in Phase 1 of the Trauma-Informed Co-parenting Sub-study.

Study Interventions and Measures:

In the Main RCT, we will rigorously study the effects of the Opening Doors to Early Intervention Program's Family Navigator (FN) intervention on the use of EI referrals and services and on child developmental outcomes among at-risk urban minority children.

In the COVID-19 Rapid Response sub-study, we will survey participants concerning safety net program use prior to and during the current COVID-19 pandemic as well as current needs that are not addressed by program participation. . The survey will inquire about current and past year participation in the following safety net programs: unemployment benefits; Medicaid or Children's Health Insurance Program (CHIP); Women, Infants, and Children (WIC); Temporary Assistance to Needy Families (TANF); Supplemental Nutrition Assistance Program (SNAP); Supplemental Security Income (SSI); Early Head Start; and county Early Intervention services. Questions derived from the latest Survey of Income and Program Participation (SIPP) will be utilized to query participants on program use before and after the onset of the pandemic. To gain an in-depth understanding of safety net program use and adjustment to new service delivery models, we will conduct telephone interviews with 20-30 parents to identify their perceptions of program assistance and needs. We will inquire about each program they are currently participating in, how services are delivered (e.g. virtually), and whether the current format meets their needs. We will also inquire about barriers and facilitators to program participation and what unmet needs they currently have. An interview guide will be developed for the interviews. All interviews will be audiotaped and transcribed for analysis.

In the Childhood Trauma sub-study, we will conduct 3-5 rounds of a modified Delphi process with up to 50 experts (fields of parenting, childhood trauma, and/or co-parenting) to develop a consensus list of childhood trauma and stress topics for inclusion in an adapted co-parenting program known as Family Foundations (FF). We will then adapt the FF and conduct interviews with up to 50 parents of participating children who report 2 or more ACEs on their baseline survey from the main RCT, using a CHOP approved conferencing software. Parents in the interviews will provide feedback on the adapted program regarding

topics, feasibility, acceptability, and appropriateness. Focus groups will be led by research staff and will be audiotaped and transcribed for thematic analysis.

TABLE 1: SCHEDULE OF STUDY PROCEDURES

Study Phase	**PreStudy Visit**	**Screening/ Study Visit 1 (Baseline)**	**Follow-up Study Visits**			
Measure			**V2 (*3 mo*)**	**V3 (*6 mo*)**	**V4 (*9mo*)**	**V5 (*12 mo*)**
Informed Consent		X				
Review Inclusion/ Exclusion Criteria		X				
Demographics		X				
*SAHL		X	*(X)*	*(X)*	*(X)*	*(X)*
StimQ		X				
Poverty		X				
EI Engagement		X	X	X	X	X
EI Referral			X	X	X	X
EI Services			X	X	X	X
*Phila Exp. ACE			X	*(X)*	*(X)*	*(X)*
**Public Policy*			*X*	*X*	*X*	*X*
*BSID-III						X

*Philadelphia Expanded ACEs measure is administered only once throughout the duration of the study, during the 3-month follow-up survey. However, this measure may be completed during a later time-point in the event that it is not completed during the 3-month time-point.

*Due to the interactive nature of the SAHL measure, in the event that the baseline visit must be conducted remotely, the participant will have the option of either completing the SAHL by utilizing a video conferencing application or completing the SAHL in-person at a later date. As a result, the SAHL is a baseline measure that may be completed during a subsequent follow-up visit. If a visit is conducted using a video conferencing application, we will try to use a HIPAA-compliant application licensed by CHOP (i.e., Skype, Bluejeans or WebEx).

*Public policy changes that may impact access to services (e.g. changes in EI funding or eligibility) will be queried of EI staff throughout the study period.

*BSID-III: In the event in-person procedures cannot take place at the time of the final study visit time-point (due to COVID-19 or other reasons) this assessment may be performed beyond the 12-month time-point, at a later date, any time before the child turns 42 months and 15 days old.

1 BACKGROUND INFORMATION AND RATIONALE

1.1 Main RCT

Early childhood is a critical period in which young children attain developmental milestones necessary for cognitive, motor, language, and socio-emotional functioning.[1] Unfortunately, developmental delays are commonly encountered among children under the age of 3 years.[2] These delays occur when a child does not reach important milestones, e.g. independent ambulation, within an expected period of time in one or more domains. Twelve to sixteen percent of young children are estimated to have developmental delays or disorders.[3,4] Although developmental delays have been associated with a number of medical and genetic conditions, most are idiopathic and do not possess phenotypic characteristics that allow for easy recognition.[5] As such, developmental delays when not identified early contribute to social and emotional problems and result in poor educational and functional outcomes.[6] Lifetime costs for individuals with developmental disabilities has been estimated to exceed $60 billion in 2003 U.S. dollars.[7]

Identifying developmental delays and instituting early intervention (EI) services in a timely fashion are of critical importance to optimize child wellbeing. The EI Program (Part C of the Individuals with Disabilities Education Act) was established by Congress in 1986 to provide funding for states to establish and maintain programs of services to meet the needs of children with developmental delays and disabilities and their families.[8,9] The evidence base for the effectiveness of EI services has been established.1,10,11 At-risk children without the benefit of early intervention services experience average declines in cognitive development of approximately 0.5-0.75 SD units.[12] EI systems have been found to prevent or reduce cognitive declines in at-risk children in the first five years of life and to mitigate stressors among at-risk families that contribute to developmental delays.[8] Reviews of EI programs found average improvements of 0.43-0.75 SD (~8-12 IQ points) in cognitive function.[10,13] However, much of the research on the effectiveness of EI on at-risk children has involved premature infants,[14-18] so it isn't clear how effective EI services are for term or late preterm at-risk children.

The National Early Intervention Longitudinal Study and other studies, which sought to describe participation rates in EI programs, found that few (2%) children participate in EI programs nationwide.[3,19-21] This is particularly true for poor and racial minority children.[22] This figure represents less than 20% of potentially eligible children. The few who do participate often experience long delays from initial recognition of a developmental delay to enrollment in an EI program: recognition first occurring at an average age of 7.4 months old and enrollment into EI and initiation of an Individual Family Service Plan (IFSP) occurring at an average age of 15.7 months old. However, this average delay masks the wide variability in age at EI entry with the majority of children with specific diagnosed conditions, e.g. cerebral palsy, entering EI prior to 12 months of age, and the majority of children with non-specific developmental delays, e.g. non-specific language delay, entering EI services much later between 24 to 36 months of age.

Disparities in early child development have been well documented.[23,24] Racial minority children are more likely to be diagnosed with developmental delays and autism spectrum disorders later than their white counterparts.[25,26] Similarly, children from impoverished

neighborhoods are more likely to experience developmental delays and initiate services later than their wealthier peers.[26-30] Differences in developmental status between lower and higher income children may be apparent as early as 18 months of age and may then widen over time. Children from minority and low-income communities who experience delays in development may be less likely to receive necessary services and to report difficulties accessing EI to receive treatment to improve their developmental status.[3,19-21,31] As a result, poor minority children may be less likely to possess adequate academic skills known as school readiness by the time of school entry, and to be more likely to have learning deficits that contribute to the so-called "Achievement Gap". Improving access to early intervention services and early childhood educational systems is an important issue in reducing the "Achievement Gap".[32]

A number of potential causes for the apparent disparities in developmental status have been investigated. Children from poor or racial minority households have less enriching home environments than children from higher socioeconomic or white non-Hispanic households.[33,34] In addition, poor or racial minority parents are more likely to have limited literacy, have fewer books at home, and engage in less book reading with children than wealthier parents.[35,36] Efforts to enhance the home environment and promote early literacy through national programs such as Reach Out and Read and Healthy Steps have reduced the gap in early child development but not eliminated it.[37,38] Additional assistance through high quality preschool programs such as Early Head Start and home visitation programs may further close the gap but have limited availability due to funding constraints.[35]

Federally-funded Part C EI services are a critical component in reducing disparities in early childhood development. However, it's not entirely clear why at risk poor and racial minority children don't fully utilize the EI system. Jimenez et al. found that families who didn't complete EI referrals were more likely to misunderstand the importance of EI services, have ambivalence concerning the need for an EI referral, report distrust of the EI system, have a preference to manage the problem on their own without outside assistance, or experience logistical barriers to the completion of EI referrals.[39,40] They further found that these themes were more commonly reported among individuals with lower health literacy and likely resulted in families experiencing more difficulties navigating the EI system.[41] Little et al similarly reported that some parents may not be receptive to EI services due to a lack of understanding of EI or stressors in the home environment.[42]

1.2 COVID-19 Rapid Response Sub-study

Twelve to sixteen percent of young children are estimated to have developmental delays and disabilities.[3,4] These delays contribute to social and emotional problems and result in poor educational and functional outcomes later in childhood.[102] Lifetime costs for individuals with developmental disabilities have been estimated to exceed $60 billion in 2003 U.S. dollars.[7] Government-funded safety net programs assist low-income families, including those who have children with developmental disabilities, with services to meet their children's needs and basic family living expenses.[101] Therefore, wide-spread crises such as the current COVID-19 pandemic can exert financial strains on these families as well as on the programs that support them.

1.3 Trauma-informed co-parenting program Sub-study

Childhood exposure to trauma and chronic stress can lead to intergenerational cycles of poor parenting, childhood victimization, and maltreatment; thus contributing to suboptimal developmental outcomes across multiple generations. In prospective studies, up to 30% of parents who reported experiencing abuse as a child subsequently maltreated their children.[32,33] Factors that mediate the relationship between a parental experience of maltreatment as a child and their own abusive parenting practices include parental antisocial behavior, depression, PTSD, early childbearing, and poor child disciplining skills.34–40 Because child behavior and later parenting behavior is largely shaped through imitation of parenting practices observed as a child, exposure to abusive parenting increases the risk that child victims will learn such behaviors as acceptable and contribute to transmission of these behaviors and worsening child outcomes across multiple generations.

Parent support programs provide an opportunity to disrupt cycles of violence within families and mitigate the intergenerational impact of childhood trauma and chronic stress. Trauma-informed parent support programs (i.e. training addressing the impact of childhood exposure to trauma and chronic stress on parenting) have been effective in reducing risk for parent-child conflict, child maltreatment, and subsequent childhood behavior problems. In a meta-analysis examining the effect of trauma-informed parenting interventions, researchers found a significant reduction in internalizing and externalizing behavioral problems among children whose primary caregivers had experienced trauma during their childhood but completed a trauma-informed parent support program. The improvement in child behavioral problems was associated with an increased use of positive parenting practices and decrease in the use of negative parenting practices and parental stress among the caregivers.

Parents who have experienced trauma and chronic stress as a child may struggle to create strong co-parenting relationships (i.e., process through which adults work together to help children acquire values, habits, and attitudes as well as provide physical care for a child) with their caregiving partners. Strong co-parenting relationships are essential to promoting the practices and environment necessary for optimal child development. In a recent study of 477 parent dyads, we found that mothers and fathers reporting exposure to three or more traumatic experiences or chronic stressors as children displayed statistically significant decreases in co-parenting scores.

1.3.1 Introduction

1.3.1.1 Main RCT

The overall objective is to study the effects of this novel strategy involving patient navigation on the initiation and completion of EI referrals and services and on child developmental outcomes among at-risk urban minority children using a participatory effort with Philadelphia's EI community. PNs have been cited in the literature and consist of individuals who have been trained to provide patients with emotional support, instrumental and technical assistance, and/or health education in a culturally sensitive manner.[48-50] They have been utilized for patients at highest risk for delays in care, i.e. poor and underrepresented minority patients. FNs have been used to support and coordinate care for patients with cancer and mental health disorders and have been shown to reduce health

disparities in access.[48,49] A few studies including a single cluster randomized controlled trial provide limited evidence for the effectiveness of FNs on improving adherence to follow-up visits and reducing time to diagnostic resolution.[51-54] The use of PNs have not been studied on follow-through with EI referrals.

In summary, we have worked with members of Philadelphia's EI community to modify a PN model to engage, inform, and assist poor urban minority parents who have children with suspected development delays to follow-through with EI referrals and services. This application addresses our long-term goal to identify strategies that promote healthy child development and reduce disparities by adapting and implementing a well disseminated yet untested model among at-risk poor minority children with developmental delays in urban Philadelphia. The specific aims of this application address important gaps in the literature, namely to identify effective strategies to improve follow-through with EI services, to assess whether parent engagement mediates effects, and to explore whether intervention effects are moderated among families with known risk factors for poor child development including poverty, less enriching home environments, adverse childhood experiences and limited health literacy.

This study is significant by its capability to provide knowledge regarding the effectiveness of patient navigation strategies. We will overcome limitations of previous studies by conducting a rigorous randomized study with adequately powered sample sizes and a concurrent control group. Knowledge gained from this study can impact EI services, specifically Child Find practices designed to increase the identification and referral of children with developmental delays, with minimal economic impact through the reallocation of current Child Find funds to support patient navigators. If found to be successful, PN models have the potential to be scaled up and disseminated to address the poor participation rates in EI nationally. This proposal addresses the Healthy People 2020 objective to increase the proportion of children who are ready for school in all five domains of healthy development: physical development, social-emotional development, approaches to learning, language, and cognitive development.[62]

1.3.1.2 Trauma-Informed Co-parenting Sub-study

While the main RCT is examining family navigation for Early Intervention referral, this sub-study will address more upstream factors related to developmental delay. Approximately 20% of parent grant study participants report exposure to two or more traumatic experiences or chronic stressors growing up, making this supplement highly relevant. We will use qualitative, intervention development, and implementation science methods to adapt the Family Foundations program, which is an evidence-based universally used primary prevention program designed to enhance co-parenting relationship among cohabitating/married expecting first-time parents, into a trauma-informed parenting program for caregivers impacted by childhood exposure to trauma and chronic stress. In the first aim, we will solicit perspectives of parenting, childhood trauma, and co-parenting experts to identify the critical components of a trauma-informed program and conduct interviews with caregivers endorsing exposure to two or more traumatic or chronic stressors during their childhood to revise the Family Foundations curriculum and protocol.

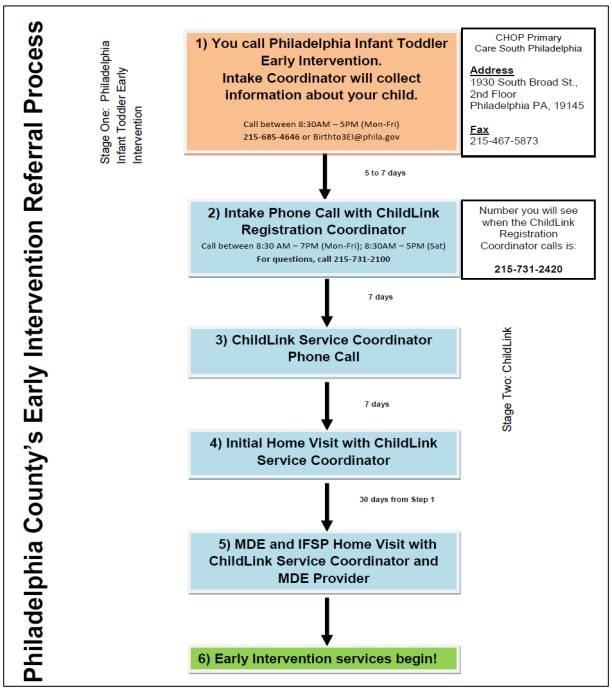
1.4 Name and Description of Intervention

The intervention will be a modified Patient Navigator model that we will refer to as a Family Navigator (FN) model, which will engage, inform, and assist participating parents to follow-through with the process of EI referrals and services. Eligible children randomized to the intervention arm will be provided with services from a FN. The FN will maintain contact with the family, the child's primary care provider, and Early Intervention staff, if applicable, throughout the duration of the study.

1.5 Relevant Literature and Data

Child Find services are a mandated component of Part C of the Individuals with Disabilities Education Act to identify and enroll eligible children with developmental delays and disabilities. Child Find practices utilized by EI agencies may employ a variety of different strategies ranging from public awareness campaigns to developmental screening to childcare and clinician referrals. In previous studies, we found that only 50% of urban patients in Philadelphia completed EI referrals once they were identified as having delays and referred using these strategies (See Preliminary Studies section). However, none of these current practices seek to engage, inform, and assist parents to overcome motivational, knowledge, and practical barriers to completion of referrals.

Fig 3. Philadelphia EI Referral Process



This application is innovative, in our opinion, in adapting a PN model to address poor EI referral and service completion. This model termed "Opening Doors to Early Intervention" was based on a review of the literature of patient navigators (or family navigators, as we will refer to them in our study) and received practical input from practicing clinicians, EI staff, and parents to adapt it. The intervention was manualized to ensure consistency of procedures and included multiple modules addressing 1) education of families regarding knowledge of early child development, 2) information on the EI system and steps necessary to complete an EI referral, 3) brief motivation interviewing to assess families' goals and treatment preferences and level of interest in initiating EI referrals, 4) assistance with overcoming barriers to completing EI referrals and maintaining EI enrollment, and 5) social work referral in the event of medical complexity or family crisis (See Appendix for Manual of Operations). PNs met with families soon after a referral was made and then followed up with families using phone, email, or text messaging to track completion of the referral steps leading to a multidisciplinary evaluation for services (Fig 3). PNs provided assistance and encouragement when families experienced barriers to the completion of steps. Although the referral steps shown here are county-specific, we retained flexibility in the manual to allow adaptation to counties with different referral processes and steps.

This proposal represents a novel application of a well disseminated patient navigation model shown to reduce health disparities in adult cancer and mental health treatment. This

application will assess the effectiveness of patient navigation among high-risk urban children with identified delays. Family navigators in this application will fulfill many of the same duties as currently are available with those in cancer care and mental health care, such as education and empowerment, care coordination, support, and problem-solving. In addition, FNs in early child development will also employ brief motivational interviewing to address parental ambivalence towards initiation of EI referrals. If shown to be effective, FNs have the potential to be scaled up within the current EI system in Philadelphia and to be disseminated nationally to other EI systems in large metropolitan areas with diverse patient populations to facilitate completion of EI referrals.

This application challenges current clinical practice that relies upon at-risk families to understand the importance of EI referrals, overcome ambivalence towards EI services, develop trust in the EI system, and effectively overcome barriers to completing referrals and engaging in services without assistance. Our model addresses these barriers to EI referral completion in several ways. First, the model provides families with knowledge and understanding of normal child development and the complicated EI referral process, which encompasses five distinct steps locally. Preliminary work by our study has shown that urban families, particularly those with limited health literacy, may not understand the rationale for EI services and may perceive distrust of public services.[39,41] Providing an understanding of the EI process can help to set proper expectations for referral completion. Second, the model attempts to address parental ambivalence towards EI referrals through brief motivational interviewing. In this way, we help families to understand what it is they want for their children, e.g. healthy development; how best to attain that goal, e.g. initiation of EI services; and their willingness and ability to complete the referral process. Third, the model provides for periodic check-ins with families and assists families to overcome barriers when they arise, e.g. rescheduling a missed appointment.

1.5.1 Scientific Premise

1.5.1.1 Main RCT

While most efforts to reduce disparities in early child development have focused on primary prevention strategies, e.g. the Nurse-Family Partnership,[37,43,44] or developmental screening programs, e.g. Assuring Better Child Health and Development Program,[45-47] little work has been done to improve the poor participation rates seen among young poor racially diverse children in EI programs. Early Intervention Part C Services include funding for Child Find activities, i.e. programs to increase the identification and referral of children with suspected developmental delays, but lack information on effective strategies to engage, inform, and assist at-risk children and their families with accessing EI services. We are unaware of rigorous studies designed to identify effective strategies to improve EI participation. Identifying effective strategies to enhance the participation of at-risk urban minority families in existing early intervention programs has the potential to substantially mitigate existing disparities in early child development.

1.5.1.2 Trauma-Informed Co-parenting Sub-study

Family Foundations (FF) is an evidence-based universal primary prevention program designed to enhance co-parenting relationships among cohabitating/married expecting first-time parents. Delivered as part of a hospital-based childbirth education program, the

program includes a series of nine interactive, psychoeducational, skills-based classes. We summarize the FF conceptual framework in figure 1. Trauma and chronic stress experienced as a child contributes to child developmental problems through three separate pathways. First, directly as traumatic experiences can trigger hostile and reactive parenting styles. Childhood trauma and chronic stress also lead to parental adjustment problems (stress, anxiety, depression, PTSD) which in turn leads to suboptimal parenting practices. At the same time, childhood trauma and chronic stress alters individual parent characteristics such as attitudes towards parenting which decrease cooperative parenting practices negatively impacting caregiving skills and subsequent child developmental outcomes. Effective co-parenting practices moderate the direct and indirect effects of childhood trauma and chronic stress on parenting, improving child developmental outcomes. Researchers have found FF to be an effective tool in promoting quality co-parenting and caregiver self-efficacy while decreasing parental stress and use of harsh discipline and child adjustment problems at age 3.56 However, FF has not been designed for use with trauma-impacted parents. We will use qualitative, intervention development, and implementation science methods to adapt the Family Foundations program into a trauma-informed parenting program for caregivers impacted by childhood exposure to trauma and chronic stress.

1.6 Compliance Statement

This study will be conducted in full accordance all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46 and the Good Clinical Practice: Consolidated Guideline approved by the International Conference on Harmonization. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

Our long-term goal is to develop effective strategies to promote child development and reduce disparities. As such, we developed the Opening Doors to Early Intervention Program, a patient navigation intervention designed to facilitate follow through with EI referrals and services. The overall objective of this project is to rigorously study the effects of the patient navigation intervention (Opening Doors to Early Intervention Program) on the use of EI referrals and services and on child develop-mental outcomes among at-risk urban minority children. Our central hypothesis is that patient navigation can improve parent engagement and knowledge, enhance follow through with EI services, and improve developmental outcomes among these children. Preliminary findings support this hypothesis and suggest the intervention is feasible and potentially effective. Findings from this study can be disseminated to similar urban counties across the U.S. to inform EI strategies and address disparities in early child development. We propose to test our central hypothesis and thereby

accomplish our overall objective for this application by pursuing the following specific aims:

2.1 Primary Objective (or Aim)

Specific Aim 1: To test the effectiveness of the Opening Doors to Early Intervention Program on EI service use and child developmental status among poor minority children residing in an urban community

2.2 Secondary Objectives (or Aim)

Specific Aim 2: To assess whether parent engagement mediates the effects of the Opening Doors to Early Intervention Program.

Specific Aim 3: To explore whether the home learning environment, parental health literacy, adverse childhood experiences or poverty moderate the effects of the Opening Doors to Early Intervention Program on child developmental status.

a. *Aim 3a*: To explore whether differences in developmental scores between intervention and control groups varies by the richness of home learning environments.

b. *Aim 3b*: To explore whether differences in developmental scores between intervention and control groups varies by the health literacy level of parents.

c. *Aim 3c*: To explore whether differences in developmental scores between intervention and control groups varies by family income level.

Specific Aim 4: To determine changes in use of and need for safety net programs and adjustment to a remote service delivery model for Early Intervention services among low-income families of children with developmental disabilities during the current COVID-19 pandemic in Philadelphia by way of the COVID-19 Rapid Response Sub-study.

Specific Aim 5: To adapt an already in use evidence-based co-parenting program used nationally in childbirth education settings, for use among caregivers who have experienced significant trauma and chronic stress as a child by way of the Trauma-Informed Co-parenting Sub-study.

2.2.1 Consideration of Key Biological Variables

We will assess the effects of two key biological variables, sex and age, on treatment outcomes. Similar to aim #3 above, we will include sex-by-treatment arm and age group (<18 or ≥ 18 months old)-by-treatment arm interaction terms in addition to main effects in models of treatment outcomes. These models will test whether the association between the intervention and outcome differs by sex or age group.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

3.1.1 Randomized Controlled Trial

Families of eligible children will be recruited at the time of an office visit that results in a referral to EI. Recruitment will occur in person or by telephone following an office visit using an electronic recruitment tool that permits clinicians to obtain permission for contact from families at an office visit. Electronic recruitment tools have become standard practice in PeRC and facilitate recruitment of patients across multiple studies. Caregivers of eligible children will be consented in person or remotely by utilizing the REDCap e-consent process, to participate and will complete study visits at baseline, 3 months, 6 months, 9 months, and 12 months (Table 1). We will use all available means including letters, telephone calls, text messages, and emails to ensure data are collected thoroughly and systematically from all participants. Contact information on each participant will be updated every 3 months using interpersonal exchanges and clinic EHR records. Participation incentives will include compensation to complete study measures, quarterly newsletters, and child birthday card mailings, all of which have been used in our prior work with urban populations to maintain >80% participant follow-up.[75]

The study research materials will consist of parent- and observer-reported instruments and EI data. Following written informed consent (which is either completed in person or remotely with the electronic REDCap e-consent process), participant caregivers will complete a baseline visit. Measures of demographic characteristics (child age, sex, race/ethnicity, family income, maternal education level, spoken language, and family structure) (Appendix 2), parental health literacy (SAHL) (Appendix 3), and the home learning environment (StimQ) (Appendix 4) will be collected at this visit. Due to the interactive nature of the SAHL measure, in the event that the baseline visit is conducted remotely, the participant will have the option of either completing the measure of parental health literacy (SAHL) remotely by utilizing a video conferencing application or completing the SAHL in-person at a later date. If a visit is conducted using a video conferencing application, we will try to use a HIPAA-compliant application licensed by CHOP (i.e., Skype, Bluejeans or WebEx). Measures of parent engagement and EI referral and service use will be collected at follow-up visits at 3, 6, 9, and 12 months. These visits will be conducted in-person, by telephone, or by email at the preference of the parent. Parents will be asked at study visits to complete the EI Engagement questionnaire, which was adapted from the CECPS and generated during a prior study (IRB 18-014884), and measures of completion of EI referrals (intake, registration, assignment of service coordinator, home visit, and MDE), eligibility for and initiation of EI services (IFSP), EI services use if eligible (number of EI service visits and whether services were completed or terminated), and use of other services (transfer to Preschool EI services, childcare or preschool enrollment). We will corroborate parent-reported visits with EI staff. Participants will also complete the Philadelphia Expanded ACE measure at one time-point throughout the study. This time-point will typically be the 3-month survey, however the measure may be administered during either the 6- 9- or 12-month follow-up survey time-points in the event that the survey is not completed during the 3-month time-point. The ACEs survey assesses for adverse events in that have already occurred in the past (i.e., childhood adverse experiences),

therefore the variation in time-point of when the ACEs survey is administered is not expected to affect the veracity of the reported responses.

Finally, all children will be assessed for developmental status around 12 months following enrollment at a time before the child turns 42 months 15 days. Parent's and children will have the option of attending the Seashore house on CHOP's main campus or the Robert's Center for Pediatric Research on CHOP's main campus, whichever is most convenient for the participant, to complete a measure of child developmental status (BSID-III) (Appendix 5). If the participant chooses the Seashore House, the Center for Human Phenomic Science will conduct the developmental assessment. If the participant chooses the Robert's Center for Pediatric Research, a clinician will conduct the developmental assessment. In the event in-person procedures cannot take place at the time of the final study visit time-point (due to COVID-19 or other reasons) this assessment may be performed beyond the 12-month time-point, at a later date, anytime before the child turns 42 months and 15 days old. EI data on referral completion, EI referral completion, EI eligibility, and EI services use will be obtained from Philadelphia Infant Toddler Intervention, a community partner on this proposal, to corroborate parent self-report. The Early Intervention data is collected and managed by the Philadelphia Infant and Toddler Early Intervention Program in the Department of Behavioral Health and Intellectual Disabilities Services.

3.1.2 COVID-19 Rapid Response Sub-study: Safety Net Program Use Among Low-Income Families of Children with Developmental Disabilities During a Pandemic

One parent from each of the currently enrolled parent-child dyads in the Main RCT will be contacted by telephone to obtain verbal consent for participation in this sub-study. Participants consented into the sub-study will be surveyed concerning safety net program use prior to and during the current COVID-19 pandemic. We will also survey these participants concerning current needs that are not addressed by program participation. The survey will be conducted via RedCap at CHOP, which is the method currently used to collect study measures every 3 months. The survey will inquire about current and past year participation in the following safety net programs: unemployment benefits; Medicaid or Children's Health Insurance Program (CHIP); Women, Infants, and Children (WIC); Temporary Assistance to Needy Families (TANF); Supplemental Nutrition Assistance Program (SNAP); Supplemental Security Income (SSI); Early Head Start; and county early intervention services. Questions derived from the latest Survey of Income and Program Participation (SIPP) will be utilized to query participants on program use before and after the onset of the pandemic.

To gain an in-depth understanding of safety net program use, we will conduct telephone interviews with 20-30 parents to identify their perceptions of program assistance and needs. We will inquire about each program they are currently participating in, how services are delivered (e.g. virtually), and whether the current format meets their needs. We will also inquire about barriers and facilitators to program participation and what unmet needs they currently have. An interview guide will be developed for the interviews. All interviews will be audiotaped and transcribed for analysis.

RedCap surveys will be exported to a Stata data file for cleaning and analysis. To determine changes in use of services, we will analyze differences in the proportion with past year and current program use to determine changes in demand for individual program services during the COVID-19 pandemic. We will model changes in service use by family income category, race/ethnicity, and education level. Interview transcripts will be analyzed using NVivo, a qualitative software program. Transcripts will be coded, and themes will be generated using a deductive consensus approach and Grounded Theory.

This sub-study will provide important information on current safety net program use and needs among low-income families of children with developmental disabilities during the current COVID-19 pandemic. This information can inform service needs and barriers to access to services for future pandemic planning, when needs are expected to increase due to employment furloughs and layoffs and access to services may be limited by social distancing policies.

3.1.3 Trauma-Informed Co-parenting Sub-study

The proposed study will be conducted in two phases: 1) modified Delphi approach to elicit from parenting, childhood trauma, and co-parenting experts key content that should be included in a primary care based trauma-informed adapted co-parenting program 2) qualitative methods to solicit perspectives from study participants currently enrolled in the Main RCT (R01MD011598) to adapt a primary care based trauma-informed co-parenting program

Phase 1

Key informants who are nationally or internationally recognized childhood trauma, parenting, and/or co-parenting experts (individuals with a minimum of two peer-reviewed first author manuscripts on the subject matter) will be recruited to contribute to trauma-informed material to be included in the Family Foundations program.

Phase 2

Parents currently enrolled in the Main RCT, or who were former participants and provided consent to be contacted for future research, will be recruited to participate in a virtual interview using a CHOP approved conferencing software (i.e., BlueJeans or WebEx). Inclusion criteria includes parents with children ages 42 months or younger who report exposure to two or more traumatic or chronic stressors as children. Parental exposure to traumatic and chronic stressors as a child is assessed as part of participation in the parent study using a modified Adverse Childhood Experiences questionnaire

3.2 Allocation to Treatment Groups and Blinding

In this study, 360 eligible children will be randomized 1:1 to the FN or usual care consisting of routine Child Find procedures. We chose a randomized design, because it is most effective at guarding against bias and will ensure that patients in both arms are similar in observed and unobserved characteristics. The initial randomization will be stratified by practice site, child sex, and age group (0-<18 months old and 18-30 months old) to ensure

balance between groups. We will control post-hoc statistically for any imbalances that arise. Allocation concealment (blinding of the treatment assignment) will be implemented using sealed, opaque envelopes, along with stratification, and randomly permuted blocks of unequal sizes (to prevent providers and patients from manipulating the randomization). Treatment assignment will be done at the time of enrollment following informed consent and patients will be followed over time with measures related to EI referral completion, EI services completion, and patient engagement collected at baseline, 3, 6, 9, and 12 months as well as child developmental status around 12 months.

3.3 Study Duration, Enrollment and Number of Sites

3.3.1 Duration of Study Participation

The Main RCT study duration for the 360 subjects will be approximately 12 months or until the BSID-III is completed (i.e., before the child turns 42 months 15 days).

3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

A total of 410 subjects are anticipated between the two subject groups designated for this study. The first group of subjects will include 360 participants for the Main RCT study, and these subjects will be recruited for the COVID-19 sub-study and also for Phase 2 of the Trauma-Informed Co-parenting Sub-study. The second group of subjects (Delphi Consensus group) will include up to 50 experts that will participate in Phase 1 of the Trauma-Informed Co-parenting Sub-study. Additional descriptions for each study are provided below:

The Main RCT study will be conducted at approximately 4-6 CHOP primary care practices in Philadelphia. Recruitment will stop when approximately 360 subjects are enrolled. It is expected that approximately 360 subjects will be enrolled to produce 300 evaluable subjects.

The COVID-19 sub-study will recruit about 128 participants, one parent from each of the currently enrolled parent-child dyads from the Main RCT.

The Trauma-Informed Co-parenting Sub-study will recruit and enroll a total of around 50 parent participants from the Main RCT and up to 50 experts in childhood trauma.

3.4 Study Population

In the Main RCT, we plan to recruit 4-6 urban practices from CHOP's Pediatric Research Consortium (PeRC) to participate in the study. These practices care for a diverse, complex urban population and have onsite social workers to assist with family crises. Using well-established methods that have proven effective in multiple large-scale trials, 4-6 practices located in Philadelphia will be recruited to participate using letters of invitation and in-person presentations. Incentives to participate will include provider education on early child development and opportunities for families to be eligible to receive patient navigation services. Children will be eligible to participate in the Main RCT if they are <30 months old, >35 weeks estimated gestational age, reside in Philadelphia, present at a CHOP Primary Care practice located in Philadelphia, have parents who speak English or Spanish, and have recently been referred to the Infant Toddler Early Intervention Program in Philadelphia County. Children >30 months old will not be eligible, since they are transitioning to Preschool Early Intervention (Part B services) and have little time for retention or

completion of the program. In addition, children outside of Philadelphia County will not be eligible, since they would be referred to EI services in a different county. Children will be excluded if they have received EI services in the past 2 weeks. In our pilot study, this exclusion resulted in 25 of 88 patients (28%) being excluded. A total of 360 eligible children, 90 children/year, will be recruited from participating practices to achieve a diverse sample of children. Based on a previous clinical trial involving the 4 practices, the number of potentially eligible children is estimated at 332/year. [44]

For the COVID-19 Sub-study, one parent from each of the currently enrolled parent-child dyads from the Main RCT, will be eligible to participate. If the parent is a former participant in the main RCT, the parent will only be invited to participate in the sub-study if they had previously provided consent to be contacted for future research in the main RCT's consent [or verbal reconsent] form.

For the Trauma-Informed Co-parenting Sub-study, we plan to recruit and enroll around 100 participants in total; 50 participants (main RCT subject group) and up to 50 experts in parenting, childhood trauma, and/or co-parenting (expert subject group) Parent participants from the currently enrolled parent-child dyads in the Main RCT will be eligible to participate. If the parent is a former participant in the main RCT, the parent will only be invited to participate in the sub-study if they had previously provided consent to be contacted for future research in the main RCT's consent [or verbal reconsent] form.

3.4.1 Inclusion Criteria

3.4.1.1 Main RCT

1) Child is <30 months old at time of enrollment
2) Child was born >35 weeks estimated gestational age
3) Parent-child dyad reside in Philadelphia and present at a CHOP primary care practice located in Philadelphia
4) Parents are English or Spanish speaking
5) Child has recently been referred to the Philadelphia Infant Toddler Early Intervention Program in Philadelphia County

3.4.1.2 COVID-19 Rapid Response Sub-study

1) Parent is currently enrolled in the Main RCT or, if a former participant in the Main RCT, provided consent to be contacted for future research

3.4.1.3 Trauma-Informed Co-parenting Sub-study

3.4.1.3.1 (Phase 1)

Recognized expert in parenting, childhood trauma, and/or co-parenting, with a minimum of two peer-review first author manuscripts on the subject matter

3.4.1.3.2 (Phase 2)

1) Parent is currently enrolled in the Main RCT or, if a former participant in the Main RCT, provided consent to be contacted for future research

2) Parent has an ACEs score of 2 or more

3) Parents has a child who is 42 months of age or younger

3.4.2 Exclusion Criteria

3.4.2.1 Main RCT

1) Child moves outside of Philadelphia County

2) Child has received EI services in the past 2 weeks

3) Child has HIV or congenital anomalies or genetic syndromes that place them at risk of developmental delays

3.4.2.2 COVID-19 Rapid Response Sub-study

1) Parent is no longer enrolled in the Main RCT and has not provided consent to be contacted for future research

3.4.2.3 Trauma-Informed Co-Parenting Sub-Study

3.4.2.3.1 (Phase 1)

1) Expert has at least 2 peer-reviewed first author manuscripts on the subject matter

3.4.2.3.1 (Phase 2)

1) Parent is no longer enrolled in the Main RCT and has not provided consent to be contacted for future research

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with CHOP and PDPH IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Main RCT

4.1.1 Screening/Enrollment (Baseline) Visit

- Medical Record Review
- Review of Inclusion/Exclusion Criteria

- Informed Consent
- Randomization
- Measures of the following:
- Demographics
- EI Engagement
- Measure of Cognitive Stimulation Provided in the Home (StimQ)
- Short Assessment of Health Literacy (SAHL) [*Due to the interactive nature of the SAHL measure, in the event that the baseline visit must be conducted remotely, the participant will have the option of either completing the SAHL by utilizing a video conferencing application or completing the SAHL in-person at a later date. As a result, the SAHL is a baseline measure that may be completed during a subsequent follow-up visit. If a visit is conducted using a video conferencing application, we will try to use a HIPAA-compliant application licensed by CHOP (i.e., Skype, Bluejeans or WebEx).]

4.2 COVID-19 Rapid Response Sub-study

- Verbal Informed Consent
- Emailed RedCap survey
- Audio-recorded semi-structured telephone interview

4.3 Trauma-Informed Co-parenting Sub-study

4.3.1 Screening/Enrollment (Baseline) Visit (Phase 1)

- Review of Inclusion/Exclusion Criteria
- Participant selected 'Yes' on interest form

4.3.2 Screening/Enrollment (Baseline) Visit (Phase 2)

- Review of Inclusion/Exclusion Criteria
- Verbal Informed Consent/HIPAA Authorization

4.4 Study Treatment Phase

Over the course of each subject's participation, the subject will have 3 follow-up visits, and a final study visit. At each of the three follow-up visits, measures of engagement, completion of EI referral, utilization of EI services, and eligibility for initiation of EI services will be collected. An additional measure of developmental outcomes will be

collected at the fourth and final study visit. Participants randomized into the intervention arm are assigned a FN who will carry out regular follow-up check-in sessions with the parents.

4.4.1 Main RCT

4.4.1.1 3-mo, 6-mo, 9-mo follow up visits

- EI Engagement
- Measures of the following:
- completion of EI Referral
- use of EI Services
- eligibility for initiation of EI Services (IFSP)
- Measure of experienced adversity (Philadelphia Expanded ACE measure - administered once during the study at the **3-month survey** timepoint; however, can be administered during later study visit if not completed during 3-month survey timepoint)

4.4.1.2 Final Study Visit (12-mo follow-up)

- EI Engagement
- Measures of the following:
- completion of EI Referral
- use of EI Services
- eligibility for initiation of EI Services (IFSP)
- BSID-III (*In the event in-person procedures cannot take place at the time of the final study visit time-point (due to COVID-19 or other reasons) this assessment may be performed beyond the 12-month time-point, at a later date, anytime before the child turns 42 months and 15 days old.)

4.4.2 Trauma-Informed Co-parenting Sub-study

4.4.2.1 Childhood Trauma and Parenting Expert – Delphi Process

- Delphi process questionnaire

4.4.2.2 FF Trauma-Informed Focus Group – Adaptation Phase (Phase 2)

- Interviews

4.5 Unscheduled Visits

Unscheduled visits are not anticipated.

4.6 Subject Completion/Withdrawal

Subjects may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to the study visit schedule or any AEs. The Investigator may also withdraw subjects who violate the study plan, or to protect the subject for reasons of safety or for administrative reasons. It will be documented whether or not each subject completes the study. If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded in the source documents and on the CRF.

4.6.1 Early Termination Study Visit

Subjects who withdraw from the study following screening may receive recommendations for follow up per their specific needs, including a referral to daycare or Early Head Start programs.

5 STUDY EVALUATIONS AND MEASUREMENTS

5.1 Screening and Monitoring Evaluations and Measurements

5.1.1 Medical Record Review

- Date of birth, Chart Review, History, Demographics
- Gestational age, sex, problem list, developmental assessments

5.1.2 Other Evaluations, Measures

5.1.2.1 Main RCT

Following written informed consent, participant families will complete a baseline visit. Measures of demographic and biological variables (child age, sex, race/ethnicity, family income, maternal education level, and family structure), parental health literacy, and the home environment will be collected by research staff blinded to randomization assignment at this visit (Table 3). The Short Assessment of Health Literacy (SAHL, Appendix 3) is a validated 18-item measure of health literacy in both English and Spanish.[76] The SAHL has good reliability (α=0.80 and 0.89) in Spanish- and English-speaking samples, and correlated well with other measures of health literacy including the REALM ($r=0.94$, $p<0.05$) and TOFHLA ($r=0.68$, $p<0.05$). SAHL scores $\leq$14 have been used to categorize low health literacy. The StimQ (Appendix 4) is a validated parent self-report questionnaire designed to measure cognitive stimulation provided in the home for children ages 5 to 72 months of age.[77] The StimQ contains 4 subscales (availability of learning materials, reading, parental involvement in 1developmental advance, parental verbal responsivity) and is available in English and Spanish. Internal consistency (Cronbach α=0.88-0.93) and test-retest reliability (ICC=0.93) of the StimQ is excellent, and it correlates well ($r=0.55$) with the IT-HOME Inventory, another measure of the home environment.[78] Poverty will be assessed by

examining family income (<100% of the Federal Poverty Level) and maternal education status (≤ High School).

Measures of engagement will be collected at baseline and at follow-up visits every 3months, while EI referral and service use will be collected at follow-up visits every 3 months. In addition, public policy changes that may impact access to services (e.g. changes in EI funding or eligibility) will be queried of EI staff throughout the study period. The visits will be conducted by research staff blinded to randomization assignment by telephone or email at the discretion of the parent. The Client Engagement in Child Protective Services (CECPS, Appendix 1) is a validated 14-item measure of parent engagement in child welfare services and contains 4 subscales: receptivity, working relationship, buy-in, and mistrust.[79] Reliability was good (α=0.95 for the total score and α=0.81-0.91 for subscale scores), and correlation with measures of global engagement and helping relationships and personal support was moderate to strong (r=0.36 to 0.78). Following discussions with the author of the CECPS (personal communication with Diane Yatchmenoff), the CECPS will be adapted for an EI population by conducting semi-structured interviews and cognitive testing with a separate group of parents previously referred to EI from one of the urban practices to identify new items and refine the wording on existing items. The adaption of the CECPS measure will be carried out as part of a separate study (IRB 18-014884).We have previously adapted an engagement measure for ADHD using a similar process (See Appendix). Parents will be asked at study visits to complete the adapted CECPS, which we are referring to as the EI Engagement questionnaire, and measures of completion of EI referrals (intake, registration, assignment of service coordinator, home visit, and MDE), eligibility for and initiation of EI services (IFSP), EI services use if eligible (number of EI service visits and duration of EI service visits), and use of other services (transfer to Preschool EI services, childcare or preschool enrollment). We will corroborate parent-reported visits with EI staff.

Finally, all children will be assessed for developmental status at 12 months following enrollment. Children will either attend, the Seashore House at CHOP with the Center for Human Phenomic Science or the Roberts Center for Pediatric Research with a clinician, to complete The Bayley Scales of Infant and Toddler Development- third edition (Bayley-III) (Appendix 5) is a validated scale of infant and toddler development from 1 to 42 months of age.[80] The Bayley-III has good reliability and correlates well with other measures of development including the Wechsler Preschool and Primary Scale of Intelligence, third edition (r=0.83). The Bayley-III has three subscales that will be utilized (cognitive, motor, and language) and a measure of socioemotional development.

5.1.3 Audio-recording of interviews

A sub-set of the participants in the COVID-19 Rapid Response sub-study will participate in an audio-recorded semi-structured, one-on-one telephone interview with a study team member. Interview audio recordings will be transcribed by ADA Transcription (http://www.adatranscription.com/). Audio recordings will be de-identified and sent via their secure server, and subsequent transcripts will be saved on a secure server accessed only by members of the study team.

Interviews from Phase 2 of the Trauma-Informed Co-parenting Sub-study will be recorded, transcribed (by ADA Transcription (http://www.adatranscription.com/ and/or a member of the research team), de-identified, and entered into NVivo 12.0 for coding and analysis. Recordings will be de-identified and sent via their secure server, and subsequent transcripts will be saved on a secure server accessed only by members of the study team.

5.2 Safety Evaluation

Subject safety will be monitored by adverse events reporting. As this study is not greater than minimal risk serious adverse events are not anticipated.

6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

In order to determine the effectiveness of the Opening Doors to Early Intervention Program on child developmental status, our primary outcome for this aim is the Bayley-III cognitive subscale measured at 12 months follow-up.

6.2 Secondary Endpoints

Secondary outcomes include the Bayley-III language, motor, and socioemotional subscales and the binary outcomes of whether patients complete EI referrals and services at 12 months.

6.3 Control of Bias and Confounding

Randomization and allocation concealment are the primary means of avoiding bias. Analytic strategies will also be used to control for residual confounding: (1) Stratification will control for imbalance not controlled by design. (2) Additional potential confounders will be evaluated for any residual association with treatment and included in model as needed. (3) Post randomization effects: The primary source of bias will arise after randomization from dropout and loss to follow-up. To address this problem and avoid missing data, we shall implement the following measures: (a) incentives to each family to complete the study, (b) collection of multiple contact numbers and tracking of changes, and (c) contact all randomized participants, even if they do not continue with their clinical contacts. Baseline data collection will include questions about factors that predict potential dropout, such as current living situations and regularity of contact with health care providers.[85,86] (4) Our analytic model for treatment effect will include not only potential confounders but also predictors of dropout, to be able to relax assumptions about the missing data process. (5) To investigate the possibly informative dropout (for reasons related to the intervention), we will implement sensitivity analyses.[87,88] (6) For missing values in any of the outcome measurement tools, we will implement formal methods of multiple imputation.[89,90] (7) We shall account for all dropouts and check all baseline information in real time for both invalid values and missing items and then prompt the child's caregiver for any corrections or clarifications. Then, if any covariates remain missing, we shall implement multiple imputation. (8) Attenuation bias from non-compliance might also occur if the child remains

in the study but fails to adhere to all aspects of the intervention.[91] To address this potential problem, and to estimate the effect of treatment in the presence of full compliance, we will implement the methods outlined by Small and colleagues and by Nagelkerke.[92] However, the "as randomized" approach will remain the primary method for assessing statistical significance of the intervention.

6.4 Statistical Methods

6.4.1 Baseline Data

Descriptive statistics for demographic, behavioral, and environmental characteristics measured at baseline will be examined across the two treatment groups to assess the success of the randomization.

6.4.2 Analysis of Primary Outcomes of Interest

6.4.2.1 Specific Aim 1

Primary outcomes

In order to determine the effectiveness of the Opening Doors to Early Intervention Program on child developmental status, our primary outcome for this aim is the Bayley-III cognitive subscale measured at 12 months follow-up. For our primary outcome, a linear mixed effects approach will be used to model differences in cognitive functioning between intervention groups accounting for clustering due to practice. Such an approach is advantageous for offering flexible means for accounting for potential issues that arise in randomized trials. For example, baseline patient characteristics that were not balanced across intervention groups by the randomization process can be accounted for through covariate level adjustment. Also, differential drop-out and loss to follow-up between groups can be accounted for by incorporating missing data methods such as multiple imputation.[83,84]

Secondary outcomes

Secondary outcomes include the Bayley-III language, motor, and socioemotional subscales and the binary outcomes of whether patients complete EI referrals and services at 12 months. Descriptive statistics for demographic, behavioral, and environmental characteristics measured at baseline will be examined across the two treatment groups to assess the success of the randomization. The secondary outcomes can be modeled using either a linear or logistics mixed effects model, which has similar flexibility. As a secondary analysis, we will examine differences in dosage (duration of EI service use and number of EI service visits) between intervention groups among those eligible for services. We will also examine the impact of public policy changes on the proportion eligible for EI and on the number of service visits pre- and post-change. In addition, we will examine the effects of the intervention by race/ethnicity group, sex, and age group (<18 months, >18 months) to assess for differential intervention effects.

6.4.2.2 Specific Aim 2

We will assess whether family engagement is a mediator of intervention treatment effects. We will address this aim by focusing on the role of family engagement using the EI Engagement questionnaire at 3, 6, 9, and 12 months as a mediator of the effect of the intervention on the study outcomes. Family engagement will occur post randomization and thus can be considered as a potential mediator as opposed to being a confounder. The response models discussed previously will be modified to include the EI Engagement questionnaire overall and domain scores as potential mediators in separate models to evaluate its mediating role in the association of interest. The association between outcome measures and the intervention conditional on the covariate will be compared to the marginal association estimated by the first aim.

6.4.2.3 Specific Aim 3

We will evaluate whether literacy, the home learning environment, adverse childhood experiences and poverty moderate treatment effects on pre-specified outcomes. To do so, the previously described models will be modified to include interaction terms between the intervention group assignment and each of these potential effect modifiers in addition to a main effect for the given variable. This model will then be used to test whether the association between intervention and the outcome differs by the given covariate. Factors of importance from the background section that will be used in this aim include family level variables (race/ethnicity, maternal education level, family income category, StimQ total scores, and SAHL scores).

6.4.2.4 Specific Aim 4

By way of the COVID-19 Rapid Response sub-study, we will determine changes in use of and need for safety net programs among low-income families of children with developmental disabilities during the current COVID-19 pandemic in Philadelphia.

6.4.2.5 Specific Aim 5

By way of the Trauma-Informed Co-parenting Sub-study, we will adapt an evidence-based co-parenting program for use among caregivers who have experienced significant trauma and chronic stress as a child. We will use qualitative methods to modify the FF program into a trauma-informed primary care-based co-parenting intervention for use among caregivers with traditional or non-traditional family structures who have been exposed to trauma and chronic stress as children.

6.5 Sample Size, Statistical Power and Analysis Plan

Our target sample size accounting for clustering by practice site for patients with complete 12-month follow-up is 300 participants. Assuming at least an 80% follow-up rate, the number needed to recruit to obtain this final sample size is about 360. Since a partial goal of the proposed intervention is to increase patient engagement, the rate of drop out is likely to be lower among the intervention group. If we conservatively assume that the drop-out rate among control patients is double that of patients on the intervention, the sample of patients

with complete follow-up will consist of approximately 130 control patients and 170 intervention patients.

Using the Bayley-III cognitive subscale as a primary outcome, we assert that the proposed intervention would be successful if it resulted in an increase of 3 points or more on this subscale. This is the minimal clinically significant outcome difference. Thus, based on the proposed sample size, we would obtain 96% power to detect a clinically meaningful difference in the Bayley-III cognitive scores. The power was estimated based on a simulation study that assumed that the sole impact of the intervention was on increasing enrollment into EI. Based on expected cognitive improvements due to EI found by Guralnick et al, we further assume that children who enrolled in EI had an average increase over a 12 month period of 10 points on the cognitive scale with a standard deviation of 1 point compared to patients who did not enroll.[10,12,58] Based on these assumptions, an increase of 3 points on the cognitive scale between the intervention and control group would be the result of an increased rate of enrollment from 50% among controls to 80% among the intervention group. These rates of enrollment are consistent with rates suggested by our pilot data (Preliminary Studies Section).[47]

Figure 1 *Assessment of power to detect a clinically meaningful difference*

Power	n	
0.96	300	Assuming a minimal clinically significant outcome difference (≥ 3 points increase in the BSID-III cognitive subscale)

If this level of mediation by engagement and enrollment rates is replicated in the proposed trial, such differences should be adequately characterized by the proposed mediation analysis. To assess power to detect moderating effects, we use dichotomized literacy as an example based on having a SAHL score ≤ 14. We assume a rate of inadequate literacy of 50% in each group and that the overall effect of the intervention on the cognitive score is the same as before. Using a simulation study based on these assumptions, the proposed sample size would give us approximately 84% power to a 6-point difference in differences for the effect of the intervention among children whose parents have inadequate literacy compared to children whose parents have adequate literacy.

Figure 2 *Assessment of power to detect moderating effects*

Power	n	
0.84	300	Assuming a rate of inadequate literacy of 50% in each group and that the overall effect of the intervention on the cognitive score is the same as before.

7 STUDY INTERVENTION

7.1 Main RCT

7.1.1 Description

With the implementation of the intervention, a modified FN model, the FNs will partner with families, engage them in the early intervention program, and provide ongoing communication with families, clinicians, and EI staff. Using data captured in the medical record, the FN will either meet with or speak with families remotely at the beginning of the study to review results of developmental screening tests and/or milestone assessments. This modified FN model process proceeds in five modules. Specifically, they will provide to families 1) education regarding knowledge of early child development, 2) information on the EI system and steps necessary to complete an EI referral, 3) brief motivation interviewing to assess families' goals and treatment preferences and level of interest in initiating EI referrals, 4) ongoing assistance to overcome barriers to completing EI referrals and maintaining EI enrollment, and 5) social work referrals in the event of family crisis or medical complexity. Specific procedures in separate modules, e.g. Early Intervention Intake Monitoring, have been manualized. The FN will contact families weekly to monthly by phone, text messaging, or email depending on family preference to monitor initiation and completion of referral steps, identify family concerns and/or barriers to referral completion, and assist families with problem-solving to identify barriers and solutions to complete EI referrals. Using email or telephone, the FN will also communicate with pediatric clinicians and EI staff to clarify treatment plans and goals and address emerging issues. A fidelity checklist developed in the pilot study will be utilized to assess self-reported task completion by the FN (0- not completed, 1- partially completed, 2- fully completed). In addition, the FN will summarize patient encounters, e.g. telephone calls with parents, in a log file. In the control arm, eligible children and their families will follow usual care procedures. As such, families are counseled by their clinicians, provided with educational handouts on development and the EI process, and referred to EI using electronic faxes from the clinic offices to the EI administrative office. EI staff then contact families by phone to initiate the EI referral process and arrange visits to complete the intake and evaluation (see Fig. 3). Families that fail to complete EI referrals and/or services in a timely manner may be dropped by EI but can be re-referred by their clinicians to complete the process later.

7.2 Trauma-Informed Co-parenting Sub-study

7.2.1 Description

7.2.1.1 Phase 1 (Delphi Process)

We will develop a consensus list of childhood stress and trauma-related topics for inclusion in our adapted primary care-based trauma-informed co-parenting program, we will use a modified Delphi process to achieve agreement amongst key parenting/childhood trauma and chronic stress experts as to which topics are essential for inclusion. Participants will be asked to complete three to five iterations of the Delphi process using an internet-based survey. We will ask experts to complete the survey all at once and within two weeks of receiving the questionnaire. Participation can last between 2-3 months. Based on our extensive review of the literature summarizing the impact of childhood exposure to trauma

and chronic stress on parenting, we will provide the key experts with a structured questionnaire asking them to prioritize each childhood trauma and chronic stress related-topic area identified during our literature review. Prioritization will be based on a four point Likert-type scale from least (1) to most important (4) for inclusion. During the first three rounds of the Delphi process, experts will be given the opportunity to add subject areas that were not initially included to our list.

7.2.1.2 Phase 2 (Interviews)

We will conduct interviews with up to 50 caregivers who have experienced trauma and childhood stress as children. Parents currently enrolled in the Main RCT ODEI study (IRB #18-014807), or if a former participant in the Main RCT, provided consent to be contacted for future research, who report exposure to two or more traumatic events or chronic stressors as a child and have children ages 42 months or younger will be recruited for this phase of the study. Participants will be asked to review and provide feedback on changes made to a co-parenting program. Interviews will be held virtually and last approximately one hour. Participants will be encouraged to provide recommendations on additional content to include in our changes to the co-parenting program as well as ways to improve the acceptability, appropriateness, and feasibility of the co-parenting program. Dr. Roy Wade along with at least one research assistant will conduct interviews virtually. Research assistants will help facilitate interviews and take notes. Interviews will be recorded, transcribed, de-identified, and entered into NVivo 12.0 for coding and analysis. We anticipate conducting interviews with a maximum of 50 caregivers but less if saturation is reached prior to interviewing 50 caregivers.

8 SAFETY MANAGEMENT

8.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study.

8.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the PDPH IRB and the CHOP IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

9 STUDY ADMINISTRATION

9.1 Treatment Assignment Methods

9.1.1 Randomization

Children and their parents will be randomized following informed written consent 1:1 to 1) a family navigator trained in the Opening Doors to Early Intervention program or 2) usual

care. Children will be stratified by practice site, age group (<18 months, 18-30 months old), and sex and randomized in blocks of 10-15 using randomly generated study numbers. Sealed opaque envelopes containing treatment assignments will be produced by the study biostatistician. Children and their parents will participate in the study over a 12-month period with data collection occurring at baseline, 3 months, 6 months, 9 months, and 12 months.

9.1.2 Blinding

Allocation concealment (blinding of the treatment assignment) will be implemented using sealed, opaque envelopes, along with stratification, and randomly permuted blocks of unequal sizes (to prevent providers and patients from manipulating the randomization). Participants will not be blinded to their treatment assignment. However, research will be blinded to treatment assignment when collecting study data.

9.2 Data Collection and Management

All records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy. The Investigator and other site personnel will not use such data and records for any purpose other than conducting the study.

To ensure confidentiality of information, data will be stripped of potential identifiers, and all written and computerized files will be indexed by a unique identification number. Only research staff will have access to this information and to a separate master list. All data for these study procedures will be maintained on CHOP's secure research server, and all analyses will be performed on de-identified data only. All collected study measures will be entered directly into a REDCap database maintained and protected on this secure research server. The unique identifiers will be used to track enrolled families over the course of the study. Confidentiality will also be maintained by use of subject code numbers in all presentations and publications. Each member of the research team, including investigators, research assistants, and stakeholder-investigators will receive appropriate training in human subjects research and patient confidentiality.

Unique identifiers will be created for each subject in the study. REDCap will be used to store the data. A master list containing PHI and subject ID number will be kept separate from data forms (electronic and paper). The master list will be kept using password-protected files. These files will be encrypted and maintained on the CHOP secure server to ensure security. Participants' information will be stored in the REDCap database and configured to export data without PHI. All de-identified records will be retained forever. De-identified data will be shared with the study sponsor. Stored data and patient identifiers will be kept for 6 years subsequent to the study completion, and possibly longer if required by the sponsor.

9.3 Confidentiality

All data and records generated during this study will be kept confidential and in accordance with institutional policies and HIPAA on subject privacy. Participation in all aspects of the proposed study is completely voluntary. The research team will institute strict procedures to maintain confidentiality. Subjects will be assigned a unique identification code that will be used as the sole identifier. The data will only be shared with the investigative team during the implementation of the study and results will only be presented in aggregate form. Any results obtained cannot be related to the original source, so no results would be provided to the patient, healthcare provider, or insurance provider, except for the results of EI referrals, EI eligibility, and EI services which are part of the family navigator intervention which will be shared with clinicians and EI staff involved in the care of study participants. All study information will be maintained on a secure password-protected server with regular backup. Per standard NIH guidelines, a Certificate of Confidentiality (CoC) will be automatically generated for this NIH-funded study.

Throughout the study, the Philadelphia Infant Toddler Early Intervention data will be shared with the Study Investigators. Additionally, any necessary study data will be transmitted accordingly to Clinicaltrials.gov.

9.4 Regulatory and Ethical Considerations

9.4.1 Data and Safety Monitoring Plan

The investigative team will develop a data and safety monitoring plan to ensure the safety of study participants and their families and to ensure the integrity of the data collected by way of a formal Data and Safety Monitoring Board (DSMB). Research staff will provide reports of preliminary data and adverse events to the DSMB, and to the CHOP and PDPH IRBs on a yearly basis throughout the duration of the study. In the unlikely event of an adverse outcome associated with this study protocol, e.g. disclosure of patient information, it will be documented and discussed with the research team, and reported to the CHOP and PDPH IRBs and the NIMHD, if appropriate. Any serious adverse events will be reported to the CHOP and PDPH IRBs, the DSMB, and to NIMHD within 72 hours. Families will be promptly informed of any disclosures of PHI.

Data and safety monitoring will be provided by the formal DSMB. The DSMB will meet annually to review all safety concerns. The DSMB will make recommendations regarding study procedures to minimize safety concerns.

The Community Advisory Board (CAB) will meet twice annually to review study progress and make recommendations. The CAB will consist of the PI, an administrator at Philadelphia Infant Toddler Early Intervention, and three parents not enrolled in the study.

9.4.2 Risk Assessment

The study is minimal risk to children, because the intervention will involve patient education, engagement, and problem-solving to facilitate EI referral and service completion. This intervention will in no way mandate clinicians or parents to pursue a specific treatment for a given patient. Furthermore, both clinicians and families will have direct access to the study team as a means to voice any questions, concerns, or reservations. Contact information will be provided at the time of consent. Should any specific concerns arise, the study team will intervene to address problems including, if needed, a change or discontinuation of study procedures. The CHOP and PDPH IRBs will be promptly informed of any concerns.

The research involves the collection of information from parents and children and data from EI services. The risk of participation is considered minimal. There is a potential risk of breach of confidentiality of information and study results about individuals. This risk is minimized by measures taken by the study team to ensure confidentiality; risks are greatly reduced by using secure files, storing data on secure computers, using unique study identifiers, and de-identification of data prior to analysis. A second risk is that participants may become uncomfortable in completing study measures. If this occurs, the protocol will allow participants to stop at any time. Should any specific concerns arise throughout the project period, the CHOP and PDPH IRBs will be promptly informed. Since the purpose of the intervention is to help children and their families' complete EI services and improve child development, we expect that adverse consequences will be extremely rare and unlikely. A third risk is that research staff may identify potential child abuse or neglect among study participants and report the incident to Child Protective Services. To prepare for this situation, all staff with direct interactions with child study participants will be required to undergo training in child abuse and neglect recognition available at CHOP. The Commonwealth of Pennsylvania requires such training of all individuals who have direct contact with children. In addition, a child abuse and neglect protocol (see Appendix) will be submitted with the initial IRB application that will outline reporting requirements and procedures in the event of suspected child abuse and neglect.

9.4.3 Potential Benefits of Trial Participation

There are no direct benefits to subjects. The results of this study may assist health care providers and EI staff in caring for children with developmental delays. This model may be replicated in different care settings and thus generate generalizable knowledge. Further, the information obtained will be disseminated as widely as possible, including publication in peer-reviewed journals and policy briefs and presentations at scientific and lay conferences. Results gathered from the COVID-19 sub-study will provide important information on current safety net program use and needs among low-income families of children with developmental disabilities during the current COVID-19 pandemic. This information can inform service needs and barriers to access to services for future pandemic planning, when needs are expected to increase due to employment furloughs and layoffs and access to services may be limited by social distancing policies. Given the minimal risk nature of the study, the risks are considered reasonable in relation to the potential benefit to be gained. Results gathered from the Trauma-Informed Co-parenting Sub-study will support future R01

grants focused on implementation of this intervention in a primary care setting and evaluation of the efficacy of this primary care-based trauma informed co-parenting intervention in improving child developmental outcomes among children reared by caregivers endorsing exposure to trauma and chronic stress as children.

9.4.4 Risk-Benefit Assessment

The potential risks associated with study procedures are minimal. Results gathered from this comparative effectiveness study will build the foundation for improving EI participation and reducing disparities in early child development. Given the minimal risk nature of the study, the risks are considered reasonable in relation to the generalizable knowledge to be gained.

9.5 Recruitment Strategy

9.5.1 Main RCT: Subjects

Recruitment will be conducted through the Pediatric Research Consortium (PeRC). Eligible children and their parents will be identified at the time of a clinical encounter (visit or telephone) involving a referral to EI through the use of an EHR recruitment prompt. Parents who verbally agree to be contacted will have their contact information sent to research staff. Medical records of the potentially eligible subjects will be screened and assessed for eligibility prior to contacting the subject. Subsequent to screening the medical record, the subject will be called by the research staff to explain the study and arrange for a study visit that will be completed either in person or remotely. Research staff will briefly explain the study procedures, guided by the information set forth in the approved consent form. This includes reading the inclusion criteria to the potential participant, and asking whether or not this individual is interested in participating. Research staff will then schedule a time to either meet with the parent in person or to complete the baseline visit remotely. In the event that the baseline visit is scheduled to be completed remotely, research staff will also need to confirm the subject's email address in order to send them the electronic Informed Consent Form via REDCap. At this visit, parents will be asked to provide written informed consent (which can be completed in person or remotely by utilizing the electronic REDCap e-consent process) to participate in the study and to sign, either in person or electronically, a Medical Release of Information form to enable the research team to obtain EI data from Philadelphia Infant Toddler Early Intervention. The consent and Medical Release of Information form will be administered by a trained member of the research staff either in person or remotely and will consist of all elements of informed consent.

Based on data from a previous clinical trial involving 4 of these practices over an 18-month period, the number of potentially eligible children will total at least 332 children per year.[44] 90 eligible children (28%) per year will be recruited from the participating practices using an electronic recruitment tool embedded in the hospital electronic health record. We previously utilized this tool in other studies to identify eligible participants at the point-of-care and obtain consent for contact from their caregivers. Children are members of a special class. The rationale for the involvement of children in the study is that the investigation

addresses child development in pediatric care settings. The study does not involve any other special class of subjects.

9.5.2 COVID-19 Rapid Response: Subjects

One parent from each of the currently enrolled parent-child dyads in the Main RCT will be contacted by telephone by a study team member to obtain verbal consent for participation in the COVID-19 Rapid Response sub-study. If the subject states their interest in potentially participating in the sub-study, the study team member will proceed to verbally consent the participant into the sub-study.

9.5.3 Primary Care Clinics, Clinicians and EI Staff

The 4-6 practices within the (PeRC network will be invited to participate through a well-established process using in-person presentations and solicitations. A waiver of consent will be sought for primary care clinicians and EI staff, since no information will be collected about them, and all information collected from them will be clinical information (e.g. referral status) to be shared directly with the clinical team. Primary care clinicians at participating practices and EI staff will be informed of the study by letters of introduction, and those who have a patient randomized to the intervention arm will receive text or phone messages and emails from the family navigator as part of the intervention component.

9.5.4 Trauma-Informed Co-parenting Sub-study: Subjects

Phase 1: a list of experts in the fields of parenting, childhood trauma, and/or co-parenting that meet the initial screening criteria (minimum of 2 peer-reviewed first author publications) will be utilized to contact potential participants. An email describing the Delphi process will be sent and participants will be provided with a unique survey link that contains additional details about the study, a copy of the consent form for review, and a question that asks whether he/she is interested in participating (participation questionnaire). Subjects that respond as interested will have their email included on Delphi process distribution list. Additional experts referred by subjects will be screened for eligibility and then invited to participate, as applicable.
Email will serve as the primary method of recruitment, but we will also mail an invitation letter to the experts as another form of recruitment. These efforts will be made as a second form of contact in case the email addresses that we collected are not accurate. The invitation letter will include the same information that will be provided to the experts in the email, however instead of a link to the online questionnaire, we will ask the experts to contact the study investigators by email to express their interest. Our team will then generate a unique link to send by email for the expert to complete the online enrollment.

Phase 2: a parent who is currently enrolled in the Main RCT or is a former participant of the Main RCT and provided consent to be contacted for future research, will be contacted by telephone by a study team member to briefly explain the sub-study and inquire as to whether or not they might be interested in participating. If the subject states their interest, the study team member will proceed to verbally consent the participant into the sub-study.

9.6 Informed Consent/Assent and HIPAA Authorization

Following the screening via review of the medical record, eligibility for study participation will be explained via phone. During the research staff visit subsequent to the screening process, written informed consent will be completed. Written informed consent can be completed either in person or remotely utilizing the electronic REDCap e-consent process. Research staff will discuss the study aims, procedures, risks and benefits, alternatives to participation, and confidentiality protocols with the parent. Research staff will speak to the parent about the voluntary nature of participation and provide the potential subject with the opportunity to ask questions about the study and its risks and benefits. Parents who consent to participate will either sign two copies of the informed consent form: one will be kept for study purposes and the other will be provided to the consenting parent, or they will electronically sign the e-consent form through REDCap. Parents will be provided with plenty of time to ask questions and to decide whether they want to participate. Parents will be explicitly instructed that they are free to choose to participate and that their decision to participate will not affect the health care they or their children receive at participating practices. Participants who are already enrolled in the study and need to be reconsented due to study changes (such as the implementation of certain measures), will be contacted by study staff and re-consented over the phone (or in person if that is the preferred method of the participant). No information sheet or copy will be offered to subjects who are verbally re-consented due to the fact that these subjects already have a copy of the main consent form.

The Trauma-Informed Co-parenting Sub-study will abide by the Informed Verbal Consent Authorization process described in the section above as it pertains to consenting the parent participants in Phase 2. As this phase will be enrolled over the phone and investigators will not meet the participants in person, it would be impracticable to conduct the research without the waiver. For Phase 1 participants (experts), consent will be obtained through the online Participation Questionnaire (recruitment phase) and continued participation throughout the survey rounds will imply consent. Participants for Phase 1 will not be disclosing any past, present, or future physical or mental health or condition of themselves, therefore HIPAA will not apply. An alteration of HIPAA Authorization is requested for Phase 2 participants, as it will be impracticable to obtain written authorization since participants will not meet in person.

For the COVID-19 Rapid Response Sub-study, eligible subjects will be contacted by a study team member to be verbally consented over the telephone. As with the original informed consent process, during the verbal consent process, research staff will speak to the parent about the voluntary nature of participation in the sub-study and provide the potential subject with the opportunity to ask questions about the study and its risks and benefits.

All activities stated in this proposal will be performed in accordance with the Health Insurance Portability and Accountability Act (HIPAA). CHOP personnel, including research staff and stakeholders, must complete training on the privacy measures of HIPAA. This training reviews the HIPAA policies relevant to research practice to protect the confidentiality of patients and research subjects. The protection of human subjects training provides formal, comprehensive education in order to protect children, adolescents, and parents from the risks associated with participating in research, and to reduce the risk to

investigators and the institution that are associated with non-compliance. Training covers institutional policies and procedures, federal regulations and critical aspects of study implementation. These training requirements are fulfilled by completing the Collaborative Institutional Training Initiative (CITI) Course in the Protection of Human Subjects, an online program that covers the history and ethics of human subject research, the organizational structure and procedures of the Institutional Review Board, the protocol process, HIPAA for clinical research, and standards for conducting clinical research at CHOP.

1.1.1 Reimbursement for travel, parking and meals

Transportation with Lyft will be arranged for participants who have a car seat for the final study visit (Study Visit 5) through CHOP's Family and Visitor services. In the event that the participant does not have a car seat, the participant will be reimbursed on their Clincard for their roundtrip travel based on mileage.

9.6.1 Payments to parent for time and inconvenience (i.e. compensation)

Participants will be paid up to a total of $200 for their participation. They will receive $40 upon completion of the initial study visit (Baseline). They will then receive $20 upon completion of each of the three follow-up visits (3 month, 6 month, and 9 month follow-up). At the final study visit (12 month follow-up) they will receive $100. Participants in the sub-study will receive an additional $20 payment for completing the sub-study REDCap survey, and an additional $30 payment for completing the sub-study telephone interview if they are selected to do so. All payments will be made in the form of pre-paid, CHOP-issued debit cards (i.e., ClinCard). In the event that the Enrollment Visit or other follow-up visits are unable to be completed in-person (due to COVID-19 or other reasons), the participant will be mailed a ClinCard. Once study staff confirms that the participant has received the ClinCard, the ClinCard will be activated and relevant payments will be uploaded.

Participants in Phase 1 of the Trauma-Informed Co-parenting Sub-Study will receive a one-time payment of $20 for participating in the Delphi process. Participants in Phase 2 of the Sub-study will receive a one-time payment of $20 for participating in an interview. All payments will be made in the form of pre-paid, CHOP-issued debit cards.

9.6.2 Gifts

No other gifts will be given.

10 PUBLICATION

This study will be registered with ClinicalTrials.gov following IRB approval of the final protocol and before any potential patients and their families are enrolled in the study. All study data will then be reported to the ClinicalTrials.gov site. Additionally, all arising publications of Study data and analyses will follow the set of guidelines outlined in the CHOP publications policy manual.

The research team plans to work closely with key stakeholders to disseminate and

implement the findings of the research study into accessible and usable formats in research, clinical, and community-based settings. We will target findings to state and national policymakers, county EI agencies across the state, parent advocacy groups, and pediatric practices using social media, policy briefs, mass emails, and newsletters. We will work with PolicyLab at CHOP to develop dissemination plans. PolicyLab has extensive experience distilling research findings into policy-relevant summaries and disseminating research findings to end-users. We will also utilize traditional approaches such as peer-reviewed publications and presentations at national meetings to disseminate findings to other researchers.

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APPENDIX

See attached.