PROJECT TITLE:

Parent-focused Redesign for Encounters, Newborns to Toddlers (PARENT) Trial: Comparing Two Models of Well-Child Care for Black Families

NCT05852392

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Parent-focused Redesign for Encounters, Newborns to Toddlers (PARENT) Trial

PRINCIPAL INVESTIGATOR:
Alice M. Ellyson
Assistant Professor
University of Washington 206-884-0564
Alice-Ellyson@seattlechildrens.org

PARTICIPATING SITES[1]:
Nationwide Children's Hospital Primary Care Network
Hawaii Pacific Health

Contents

1. Objectives

1.1. Purpose, specific aims, or objectives:

A. Specific Aims

Aim 1: Adapt the Parent Focused Redesign for Encounters, Infants to Toddlers (PARENT) intervention to meet the needs of a diverse, largely Black population of underserved families. We will use a stakeholder-engaged process to adapt PARENT, with stakeholders defined as Black parents, pediatric practice providers and staff, and payers.
Aim 2: Determine the effect of adapted PARENT on receipt of nationally recommended preventive care services, emergency department utilization, and parent experiences of care. We will conduct a stepped wedge randomized trial among publicly insured children ages 0-15 months across 12 clinical sites.
Aim 3: Determine whether the effectiveness of adapted PARENT differs by family-level factors (e.g., race and ethnicity, parent- Coach racial and ethnic concordance).
Aim 4: Explore parents' experiences in receiving adapted PARENT. We will conduct qualitative interviews of Black parents to understand their experiences in receiving care through adapted PARENT.
The following Specific Aims pertain to the supplemental Patient-Centered Economic Outcomes (PCEO) activities we plan to conduct under the study:
Overall PCEO Aim: To examine changes in patient-centered economic costs (and benefits) associated with adapted PARENT.
Aim 5. Examine the economic impact of adapted PARENT from the parent stakeholder perspective. We will examine the intervention effect on the total amount of time that parents spend at a Well-Child Care (WCC) visit and the time that they spend with the different members of their WCC team (e.g., pediatric provider, PARENT coach, nurse/medical assistant).
Aim 6. Examine the economic impact of adapted PARENT from the pediatric provider and clinic stakeholder perspective. We will examine intervention effect on the time that clinical providers (i.e., pediatricians) spend completing their documentation of early childhood WCC visits, as well as the effect on average time spent in WCC visits to estimate potential efficiency of adapted PARENT as a new model of care that allows the pediatrician's time to be more effectively utilized (e.g., time saved across a day of WCC visits allows a pediatrician to see one additional sick visit per day).
Aim 7. Examine the economic impact of adapted PARENT on healthcare utilization, from the perspectives of parents and families. In our main study, we will assess the impact of adapted PARENT on healthcare utilization outside of the well-visit, including emergency department utilization, urgent care utilization, and hospitalizations. For this supplement, we will assess parent-focused costs of this utilization, including transportation, as well as time away from work, and any other out-of-pocket costs to the parent for utilization.

1.2. Hypotheses to be tested:

H1: This stakeholder-engaged process will result in an adapted PARENT that builds upon the strengths of Black families to meet their preventive care needs and optimizes intervention outcomes for Black families.

H2: Adapted PARENT will improve receipt of preventive care services, healthcare utilization, and parent experiences of care, compared to usual guideline-based care.

H3: Adapted PARENT will be effective for all intervention participants, with strongest effects in Black families and for families with racial and ethnic concordance with the Coach.

H4: Findings will provide an understanding of the elements of adapted PARENT that were most salient to families in their preventive care needs.

2. Background

2.1. Relevant prior experience and gaps in current knowledge:

Clinical Practice Redesign can lead to innovative systems that improve preventive care for racial and ethnic minority children in low-income communities. Although several strategies to redesign the structure of WCC have been proposed and studied, there are few evidence-based comprehensive models that are financially sustainable alternatives to current WCC.. **The Parent Focused Redesign for Encounters, Infants to Toddlers (**PARENT) is a **comprehensive WCC delivery model designed to improve the delivery of WCC for infants and toddlers in low-income communities.** PARENT includes a non-clinician as part of a team-based approach to WCC. The "Parent's Coach" (a health coach with training in WCC services, henceforth "Coach") partners with the clinician to independently provide comprehensive and family-centered care that includes anticipatory guidance, social needs screening, developmental screening, and connection to needed community resources. The Coach reduces the reliance on a clinician as the sole primary provider of routine WCC services. The pathway by which the intervention works can be described in the context of our Conceptual Model. . The intervention changes the **structure** of WCC by adding the Coach to the team (personnel), and changing the **process**, or provision of care, which impacts the **receipt of preventive care,** and thus health outcomes .

In previous trials of PARENT, among a predominately Latino population of Medicaid-insured children, we have reported intervention effects of better parent experiences of care, greater receipt of preventive care services, and more effective utilization of care. Although these trials were not powered for sub-analyses by race, exploratory analyses indicate that while Black and Latinx families had similar intervention effects for receipt of services, Black families did not have the positive intervention effects on parent experiences of care or the reduction of emergency department (ED) visits that Latino families did. Qualitative interviews indicated that Black parents experienced delays in trust-building trusting with the Latino Coaches. **Thus, adaptation, implementation, and testing of PARENT in a trial with a large sample of Black families is needed to optimize outcomes for Black families.**

PARENT will be adapted, implemented, and tested in clinics that serve a large proportion of low-income Black families, providing findings to aid our understanding of how the intervention can be adapted to meet the needs of low-income Black families. Nationwide Children's Hospital Primary Care Network (NCH-PCN) is one of the largest Children's Hospital owned primary care networks in the country. Its 12 practices serve a patient population that is over 96% publicly-insured, 50% Black, and 16% Latinx. This proposal is a unique opportunity to meet a clinical need at NCH-PCN and address key research questions of PARENT adaptation, implementation, and impact for Black families.

The adapted intervention, if found to be more effective than usual care in providing family-centered, comprehensive preventive care services to families, has the potential to be implemented and disseminated to other clinical settings that serve a large proportion of children in low-income areas. However, our stakeholders for early childhood WCC (parents, providers and clinics), will require additional information on family-centered economic outcomes to make decisions regarding implementation and dissemination of this new model for early childhood preventive care. **To address this need, we will examine PCEO during the stepped wedge trial of the adapted intervention that will provide additional information to help WCC stakeholders make decisions about the delivery of care for early childhood WCC services**. Our goal is to assess the PCEO of integrating a PARENT Coach into early childhood preventive care visits across 12 clinical sites of NCH-PCN.

2.2. Relevant preliminary data:[2]

PARENT is an innovative, comprehensive WCC delivery model with randomized clinical trial (RCT) evidence that it is a more effective system for the delivery of WCC for family-centered,

comprehensive preventive care for infants and toddlers in low-income communities. It was designed, implemented, and tested in a community-partnered process that engaged parents, providers, and payers. In an RCT of PARENT among 251 low-income families in two urban area pediatric practices, we found strong and consistent intervention effects (Table 1) on the quality of preventive care provided to families, and on reducing ED utilization (which in a general population of children is largely avoidable ED visits).

Table 1: RCT Results	Control	Intervention	p-value
Utilization	**% (n)**		
Well-visits up-to-date	75.7 (84)	74.8 (86)	0.88
2 or more ED visits	21.6 (24) *B: 31.25 (5) **L: 21.6 (19)	10.4 (12) B: 17.4 (4) L: 8.9 (8)	0.02 0.31 0.017
Receipt of WCC Services	**Mean Scores (SD)**		
Anticipatory Guidance	77.4 (24.5) B: 71.4 (24.9) L: 77.8 (25.0)	89.3 (12.9) B: 89.6 (15.1) L: 89.4 (12.4)	<0.001 .008 <0.001
Health Information	89.6 (22.2) B: 81.3 (33.5) L: 90.3 (20.2)	96.3 (13.8) B: 97.8 (10.4) L: 95.8 (14.6)	0.008 .03 .039
Social Needs Assessment	77.9 (29.0) B: 63.5 (35.1) L: 80.9 (27.5)	94.9 (13.5) B: 94.2 (14.7) L: 95.0 (13.3)	<0.001 .001 <0.001
Receipt of WCC Services	**% (n)**		
Developmental Screening	81.1 (90) B: 56.2 (9) L: 85.2 (75)	92.2 (106) B: 91.3 (21) L: 92.2 (83)	0.014 0.011 0.14
Parent Concerns Addressed	73.8 (59) B: 62.5 (5) L: 74.6 (50)	90.2 (83) B: 100(14) L: 88.2 (67)	0.005 .014 .036
Experiences of Care	**Mean Scores (SD)**		
Family Centered Care	92.4 (13.0) B: 94.3 (8.4) L:91.6 (14.0)	96.3 (8.2) B: 95.7 (9.0) L: 96.4 (8.1)	0.008 .65 0.006
Helpfulness of Care	82.1 (19.4) B: 78.5 (22.5) L: 82.6 (19.2)	91.3 (12.3) B: 86.7 (16.1) L: 92.3 (11.0)	<0.001 .19 <0.001
*B: Black participants; **L: Latinx participants			

2.3. Scientific or scholarly background:

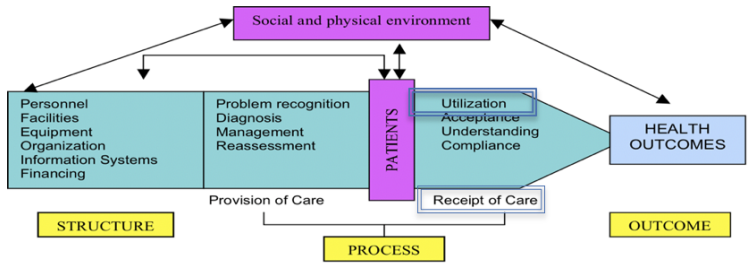
Current guidelines for well-child care are expansive and exceed the capacity of what a clinician can provide in a face-to-face, 15- to 20-minute well-child care visit. WCC is the cornerstone of pediatric primary care in the United States (U.S.), comprising over one-third of all outpatient visits for infants and toddlers. These visits provide a unique opportunity to address social, developmental, behavioral, and health issues.

The AAP recommends that children receive at least 10 WCC visits over the first 3 years of life. Bright Futures national WCC guidelines, supported by the U.S. Department of Health and Human Services Maternal and Child Health Bureau, specify that each visit includes a physical exam, anticipatory guidance (counseling and education on a broad variety of topics), and social needs and developmental screening. Anticipatory guidance guidelines are expansive, ranging from infant feeding and sleep to intimate partner violence. Despite this, most WCC visits are no longer than 15 minutes long. Not surprisingly, many families do not receive all recommended preventive services, including those most supported by the evidence and likely to improve health outcomes. Lack of time is likely a key factor lowering WCC quality. Longer WCC visits are associated with more anticipatory guidance and social needs assessment, and better ratings of family-centeredness.

Current WCC cannot meet the needs of children and families in low-income communities.

In Donabedian's Quality Framework, healthcare outcomes are determined by the structure and processes of care. The structure→process→outcome model, further developed by Starfield, serves as the conceptual model for this proposal by demonstrating how the structure and processes of care affect the eventual outcomes. See Figure 1.

Figure 1. Conceptual Model: Dynamics of Health Outcome. *(Starfield, B. 1973)*



Our current WCC structure cannot support the vast array of preventive care needs among low-income and racial and ethnic minority families. Many WCC visits do not provide adequate preventive care services and most parents leave the visit with unaddressed social, developmental, and behavioral concerns. These deficits in care affect children in low-income families most frequently.

2.4. Prior approvals:
N/A

3. Study Endpoints[3]

3.1. Primary and secondary endpoints:

Our primary outcomes are: **1) receipt of three key preventive care services** (parent-prioritized anticipatory guidance, social needs screening, and structured developmental screening), **2) Emergency Department (ED) utilization**, and **3) parent experiences of care.**

Secondary outcomes include receipt of other preventive care services, other healthcare utilization, and "at-risk" for developmental delay.

Supplemental outcomes include total WCC visit time, Provider-parent WCC visit time, Coach-parent WCC visit time, RN/MA WCC visit time, Provider EHR documentation time, and ED utilization.

3.2. Primary or secondary safety endpoints:
N/A

4. Drugs, Devices and Biologics[4]

4.1. Manufacturer and name of all drugs, devices and biologics:
N/A

4.2. Description and purpose of all drugs, devices and biologics:
N/A

4.3. Regulatory status of all drugs, devices and biologics:[5]
N/A

4.3.1. Drugs or Biologics:
☐ IND Exempt. Explain:[6] ✍Click here to enter text.

☐ IND.

4.3.2. Devices:
☐ IDE Exempt. Explain:[7] ✍Click here to enter text.
☐ Abbreviated IDE / Non-Significant Risk. Explain:[8] ✍Click here to enter text.
☐ IDE / Significant Risk.

4.4. Plans to store, handle, and administer any study drugs, devices and biologics so they will be used only on subjects and be used only by authorized investigators:
N/A

5. Procedures Involved

5.1. Study design:[9]

Phase 1 of this study is an adaptation and implementation process. Followed by the Phase 2 Stepped Wedge Trial. We are currently seeking approval for the revised intervention materials adapted through Phase 1 (will be used for the implementation of the intervention) and the implementation of the intervention (Phase 2) in this modification.

5.2. Research procedures:[10]

Phase 1 (Adaptation and Implementation Process): Parents/caregivers/LAR/guardians, providers, and staff will form a Project Working Group (PWG). Providers and staff who are PWG members will be working on the project as part of their work duties at the practices. The parents/caregivers/LAR/guardians will meet via the PWG meetings and parent expert panel-only meetings to discuss how the intervention should be adapted and implemented. The parents/caregivers/LAR/guardians will not be asked to participate in any data collection activities, for themselves or for their child. They will not see or be provided with any patient data. The meeting discussions will focus on best ways to provide care only.

The PWGs consists of 2 to 3 Practice Study Teams (PSTs). The PST will include key stakeholders from each of the 12 practices, including 1) the practice's health coach, 2) two Black parents, caregivers, Legally Authorized Representatives (LAR), or guardians at that practice, 3) a pediatric provider, 4) the practice site manager, and 5) a WCC team staff member (i.e., Medical Assistant). Together, these six individuals represent the PST for the practice. These PSTs for each of the 12 NCH-PCN sites will join with the other PSTs in their "cluster" (2-3 PSTs in each cluster) to form the aforementioned PWG. The PWG activities include intervention adaptation to meet the needs of Black families, development of a system for pre-visit screening (using Bright Futures materials), planning and practice for the clinic team (Coach, clinician, staff) workflow, coordination, and communication, and all Coach and clinic-level trainings to prepare for and practice implementation.

Study team members will ensure that PWG members are oriented to the project by providing an overview of the purpose of the study, the role of stakeholder input in the adaptation and implementation process, and general information about the organizations conducting and supporting the project.
During the first month of the 12-month Adaptation and Implementation period, the 4-6 parents/caregivers/LAR/guardians in the PWG will meet separately as a parent-only group (called the "Parent Expert Panel"), for four 1- to 2-hour weekly discussion sessions, to define how PARENT should be adapted to meet the needs of Black families.

Over the next three Parent Expert Panel meetings, we will guide parents/caregivers/LAR/guardians through a series of discussions on each element of PARENT (see Table 2 below), as well as its structure, process and content, to understand ways in which they think that PARENT can be adapted to better leverage the strengths of Black families and meet their preventive care needs. After completion of the four Parent Expert Panel meetings, the research team will create an action plan to achieve the suggested adaptations, which will be presented at the first full PWG meeting.

Upon enrollment, the 4-6 parents/caregivers/LAR/guardians in each PWG will be provided with tablets in order to facilitate equitable access to study meetings and interviews that parents/caregivers/LAR/guardians need to remotely participate in. The tablets will be loaned to parents/caregivers/LAR/guardians for a period of 1 year and at the end of this period, they will be asked to return the device to the study team. The parents/caregivers/LAR/guardians will be provided a tablet/device user agreement outlining that the tablet may only be used by the designated recipient and is not to be shared with or used by anyone else. Additionally, this agreement will outline that downloading or accessing illicit materials is prohibited and will result in termination from the study.

Table 2. Potential Topics for Parent Expert Panel Consideration in Adaptation

Cultural Factors to Consider in Engaging Black Families in Preventive Care: A Strength Based Perspective	**Intervention Structure, Process, and Content Potential Adaptations**
Cultural pride	-Provide families a children's book list (board books for infants and toddlers) that show positive images of black children and families -Ensure that preventive care written materials (i.e., parent education handouts), videos (text message links), and books (reach out and read books) are black-centric (i.e., focused on positive images and stories of black children and black families). -Provide key early childhood racial socialization tips at 9, 12, and 15 month visits through text messages and parent handouts and discussion (e.g., building positive feelings about blackness through book-sharing).[52] -Provide coach training in implicit bias, structural racism, and the process of racial socialization in early childhood
High expectations for child behavior	-Provide positive parenting techniques, showing examples of use with Black parents (text message video links) -Discuss behavior expectations in context of developmental level of child; help parents/caregivers match expectations, and parenting strategies (including discipline) to child's developmental stage

Extended Family Support	-Ask parents about other family members who serve as caregivers -Offer preventive care text message program to extended caregivers as well as parents
Ability to develop and use effective coping skills in the face of economic hardship	-When social needs are identified, allow families to share coping skills (in addition to providing resources) -Always elicit family strengths first, prior to conducting social needs screening. -Add family strengths to pre-visit tool
Value of Education	-When conducting developmental screening and surveillance, provide parents with context of its importance to pre-school readiness

During this time, PWG providers and staff, along with the other providers and staff at NCH participating clinics, will meet, without the parents/caregivers/LAR/guardians, for a 1- to 2-hour cultural humility session, devoted to understanding the historical context, diverse needs, and enduring strengths of Black families in the U.S. The session will be led by Dr. Kendra Liljenquist, Co-investigator on the PARENT study and Assistant Professor of Pediatrics at the University of Washington School of Medicine, Adjunct Assistant Professor at the University of Washington School of Public Health, and Investigator at Seattle Children's Research Institute, Center for Child Health, Behavior, and Development. Materials to be seen and/or heard by participants during the training session will be submitted for IRB review and approval prior to use.
Additionally, a virtual training option will be provided to participants that cannot access the in-person training for any reason (accessibility, etc.). Participants will be expected to attend the in-person training, when possible, but will also be provided with the option to view the virtual training, either in place of, or in addition to the in-person training.
After Month 1, the full PWG (inclusive of parents/caregivers/LAR/guardians), will meet monthly for the next 8-11 months.
The Seattle Children's and NCH (SC-NCH) research team will join the full PWG monthly meetings for each PWG. During the first full PWG meeting, we will review the structure, process, and desired outcomes of PARENT. We will utilize the Reach Effectiveness – Adoption Implementation Maintenance/Sustainment (RE-AIM) Framework to help guide project planning with the PWGs. The RE-AIM Framework was developed to help researchers improve the adoption and (sustainable) implementation of evidence-based interventions into real-world settings. It consists of 5 steps: (1) Reaching the target population willing to participate in the intervention, (2) Enhancing the efficacy of the impact of the intervention, (3) Adoption of the intervention by target population, systems and within target settings/communities, (4) Implementation of intervention, and (5) Maintenance/sustainment of intervention. We will discuss recommendations from the Parent Expert Panel on how to adapt the intervention to meet the needs of Black families. We will also discuss recommendations for adaptation that the full PWG identifies to meet the needs of clinical workflow, as well as the needs of Black families. Each practice site may have a slightly different adapted structure and process designed for the intervention, but the PWGs will maintain core elements of the intervention for consistency across all practice sites.

Over the 8-11-month meeting schedule, the PWG will complete the following intervention adaptation and implementation tasks, with guidance and engagement from the SC-NCH research team. Here, we detail the specific elements that participants (as part of the Parent expert panel, PWG, and PSTs) will contribute to:

1. Establish and determine content, periodicity, and procedures for the pre-visit screening tool. We will use the Bright Futures Pre-Visit Questionnaire (BFPQ) for parent pre-visit screening and visit prioritization. Each Practice Study Team will make adaptations to the content, periodicity, and procedures for this pre-visit tool to meet the needs of the families and the practice.

2. Generate documentation system for Coach, complementing current EHR. The Practice Study Teams will determine how the Coach will document his/her time with the family during a WCC visit, and how this information will be communicated with the provider at the time of the visit.

3. Outline the Clinical Workflow of the Coach. The Practice Study Teams will outline the work and workflow of the Coach for visits and follow-up needs between visits. They will also contribute to adaptation of a checklist of specific elements of the Coach workflow to be included in a fidelity review. The fidelity review will occur monthly after the intervention has been implemented, which will continue throughout Phase 2, at each clinic. This review will include a random extraction of 10 children's charts, per PARENT Coach, that were seen by the PARENT Coach that month. This extraction will be conducted by an NCH-PCN study team member, who will de-identify the charts, and then transfer to the Seattle Children's study team, via the existing SCRI secure File Transport Protocol (FTP) platform that only study team members have access to. Charts will be de-identified by redacting all personal identifiers on charts. A Seattle Children's study team member will then use the de-identified charts to complete the fidelity review table, submitted within this modification, and provide any needed feedback to the NCH-PCN study team and PARENT Coaches. The following information will be included in the de-identified charts sent to the Seattle Children's study team: Age, Race, Ethnicity, Preferred Language, , WCC Visit Month. Additionally, each chart will include responses to items outlined within the Parent Coach Documentation Form attached. Identifying information found in any open-response items in charts will be redacted prior to transfer to the Seattle Children's study team.

4. Coordinate process of information sharing among WCC Team. The Practice Study Teams will create a process for team "huddles", warm hand-offs for families with urgent needs, and other coordination needs.

5.*Customize WCC education and guidance via text-message*. The Practice Study Teams will provide feedback about the education and guidance provided by the Coach to parents. The Practice Study Teams will be asked to provide any edits to the text message library for local customization (e.g., local resources), and based on Parent Expert Panel recommendations (e.g., empowering message reinforcing Black family strengths).

6.*Complete brief survey to assess level of stakeholder engagement*. Following each full PWG meeting, PWG members will be asked to complete a brief survey asking them about their level of engagement during the PWG meeting. The study team will monitor stakeholder engagement using this information and use it to iteratively improve the experiences of PWG members as needed. No identifiable information will be collected. The study team will provide PWG members with hardcopy and/or secure online methods to access and complete surveys (such as Zoom, Teams, or REDCap).

7. ***Implement the Intervention as early as the last 3 months of the Adaptation and Implementation Phase***. Finalized intervention procedures and materials will be submitted to the IRB for review as modifications at the completion of each PWG's Phase 1, and prior to implementation of the intervention. The first PWG is anticipated to have finalized intervention procedures and materials in Q1-Q2 of 2024. One of the adaptations/ideas from this activity resulted in the creation of coach flyers that will be posted at participating NCH-PCN Sites, outlining the role and duties of the PARENT Coach at their clinic.

8.Contribute to a Process Evaluation of the Intervention Adaptation and Implementation Phase. Since PWGs start their Adaptation and Implementation Phase sequentially, each new PWG can learn from the previous PWGs. Thus, we will conduct a process evaluation towards the end of this Phase for each PWG. This will include either an in-person or virtual focus group discussion for each PWG's Parent Expert Panel on their experiences and engagement in the process, individual interviews, conducted virtually, with each PWG's group of Coaches, as well as the Coach Coordinator, on training, implementation, and ongoing conduct of PARENT, a virtual focus group with pediatric providers, and a virtual focus group with practice site managers, and WCC Staff Members from the clinics within the PWG to understand their experiences and engagement in the process. Additionally, when new PARENT Coaches are enrolled into the PWG, either during or after Phase 1, they will also be interviewed to learn more about their experience with training, implementation, and ongoing conduct of PARENT. In-person focus groups will be audio-recorded using a hand-held audio recorder and virtual focus groups and interviews will be audio-recorded using video conferencing platforms, such as WebEx, TEAMs, or Zoom Enterprise. If a focus group participant is unavailable or misses the initial focus group session, the study team may contact them to schedule a make-up interview, pending the Principal Investigator and Co-Investigator (K. Senturia) assessment of the findings already collected. The research team will share the focus group discussion and interview findings with subsequent PWGs and use these data to iteratively improve the Intervention Adaptation and Implementation process for subsequent PWGs. The question set, which will be used for the focus groups and interviews, are submitted within this modification.

Phase 2 (Stepped Wedge Trial):

Quantitative: We will use a stepped wedge design, in which each practice site starts in the control group, and then sequentially (by random assignment) moves to become intervention. The NCH-PCN practices will be randomly assigned to one of five PWGs. PWGs #1-#2 will have 3 practices each, and PWGs #3-#5 will have 2 practices each.

We will obtain clinical and administrative data from the electronic health record (EHR) and health plan (an accountable care organization) on a new group of eligible children ages 9-15 months every 9 months for all practices, representing either control or intervention data (depending on whether the practice has implemented the intervention). The sample at each data collection will represent all children in the practice on the day of data collection who met the following eligibility criteria: (1) age ≥9 and≤15 months on day of data collection, (2) ≥1 visit at the practice in previous 9 months, and (3) continuously insured by Partners for Kids, the accountable care organization (ACO) in previous 9 months (>90% of all NCH-PCN patients are insured by this ACO).

Each practice will contribute 5 data collection time points to the study, for a total of 2,796 children's records per data collection every 9 months, and a total of at least 13,980 children's records over the course of the study. We will collect existing data from the EHR and health plan (an accountable care organization; ACO) to evaluate the impact of the intervention on patients' receipt of preventive care services, healthcare utilization, and experiences of care. Using the same cadence and data collection process, we will collect time-stamped data from the EHR to

evaluate the patient-centered economic outcomes of adapted PARENT. NCH-PCN practice sites will adapt and implement the intervention to become part of their new way of providing care. Data will be pulled directly from the EHR and health plan systems on children from the participating practices who are publicly insured. Data will be exclusively collected retrospectively (9-month look back) from already existing clinical records, and data will be recorded in a way that prevents individuals from being identified.

Prior to any new cluster of practices (i.e., a PWG) implementing the intervention, a modification will be submitted that includes all adapted intervention materials. The first set of finalized intervention procedures and materials is anticipated in Q1-Q2 of 2024. The procedures for control and intervention groups are still the same (above).

Qualitative: Participating parents who have experienced adapted PARENT will complete a 30-45-minute qualitative interview to share their experience with the intervention. Each interview will focus on parents' experience (e.g., comfort with, trust, information sharing) with the Coach, how the Coach worked with their clinical provider, and their perspectives on unmet needs in preventive care services. We will also assess whether parents would recommend this type of care to family and friends, and whether it is something they would like their clinic to continue. Interviews will be conducted over the phone or videoconference (TEAMs, WebEx, or Zoom Enterprise) and will be recorded, transcribed and coded for analysis. Phase 2, Qualitative activities will also include a review of information contained in the child's medical record to help the research team understand engagement levels with the PARENT Coach. Only approved members of the study team will access this information.

5.3. Data sources that will be used to collect data about subjects:[11]

PWG meeting and focus group notes, EHR data, health plan data and participant interviews will be the sources of data about subjects.

5.4. Data to be collected, including long–term follow–up data:[12]

Phase 1: Notes and audio recordings taken from PWG meetings and Parents-only meetings and Process Evaluation focus group and interview findings. We will know the role/position of provider and staff PWG members as this will be available on the clinic website.

Phase 2:

- Quantitative Data: Every 9 months the following data will be collected:
  - Race, ethnicity, age, residence geocode, level of medical complexity and parent's preferred language
  - Receipt of preventative care service
  - Parent experience of care at the practice
  - Health care utilization (ED utilization, hospitalizations, and urgent care)
  - Time-stamped data: Provider-parent visit time, Coach-parent visit time, RN/MA-parent visit time, Total visit time, Provider documentation time
  - See attachment for full table of Data Elements
- Qualitative Data: Parent qualitative interviews and information from chart reviews to understand engagement levels with PARENT coach.

6. Data and Biospecimen Banking[13]

6.1. Complete list of the data and/or biospecimens to be included in the bank:[14]

N/A

6.2. Location of data and/or biospecimen storage:[15]
✍Click here to enter text.

6.3. List of those with direct access to data and/or biospecimens in the bank:
✍Click here to enter text.

6.4. Length of time data and/or biospecimens will be stored in the bank:
✍Click here to enter text.

6.5. Procedures for protecting the confidentiality and privacy of the subjects from whom the data and/or biospecimens were collected:[16]
✍Click here to enter text.

6.6. How the data and/or biospecimens will be made available for future use:
✍Click here to enter text.

6.6.1. Who can request data and/or biospecimens from the bank:
✍Click here to enter text

6.6.2. Format in which data and/or biospecimens will be provided:
✍Click here to enter text.

6.6.3. Process for investigators to request data and/or biospecimens:[17]
✍Click here to enter text.

6.6.4. Restrictions on future use:[18]
✍Click here to enter text.

6.6.5. Plan for providing data results from banked data/biospecimens:
✍Click here to enter text.

7. Sharing of Results

7.1. Plan to share results with subjects/others:[19]

The adapted manual for PARENT will be widely available, free of charge, and posted for use by community clinics, pediatric practices and providers. The PARENT manual describes the critical decision points for intervention adaptation and implementation, and follows the RE-AIM framework.

We will also work with local American Academy of Pediatrics (AAP) Chapters and National Office, as well as Bright Futures at the AAP headquarters, to disseminate findings to pediatric professionals and pediatric practices nationally. Both Dr. Coker and Kemper are deeply engaged with the AAP locally and nationally. The findings can also be shared with organizations such as the National Medical Association's Pediatric Section, which represents Black pediatricians nationally, and Academic Pediatric Association, both of which the PI is fully engaged with.

This modified intervention developed for this project will be ready for dissemination nationally for other publicly-insured children. At the end of the study, as part of our dissemination efforts, we will make our implementation materials (training, workflow, measurements, etc.) publicly available at no cost to help other clinics and practices implement this intervention in their own sites without having to go through a lengthy adaptation process.

We will disseminate our findings to the practices involved in the study, the PWG, the ACO health plan, and other relevant organizations (e.g., Celebrate One and the Healthy Neighborhoods, Healthy Families initiative).

To disseminate findings to pediatric professionals and pediatric practices in settings outside of SC-NCH, we will focus on conferences, meetings, journals, and websites and other resources targeted to pediatric medical professionals, trainees, and families.

We will ensure that our final study report contains sufficient detail on methods, data, and results to allow for assessments of the study's internal and external validity, including the nature of, reasons for, and potential effects of any missing data.

8. Study Timelines

8.1. Duration of an individual subject's participation in the study:

Phase 1 PWG members (n=76-78) will participate in the project for approximately 5 years (Years 1-5 of the project's duration). The first 12 months of their participation will be contribution to the Phase 1 PWG.

Phase 1/Process Evaluation subjects, Parent/caregivers/LAR/guardians (n=24) and Coach (n=12) Staff and Provider (n=36) PWG members, NCH-PCN Coach Coordinator (n=2) will participate for the length of one focus group session or interview.

Phase 2/Quantitative subjects (n=13,980 records) will participate during ages 9-15 months.

Phase 2/Qualitative interview participants (n=36) will participate for the length of a single interview.

8.2. Duration anticipated to enroll all study subjects:

We anticipate it taking approximately 1-2 months to enroll PWG members.
Phase 2/Quantitative subjects are not actively enrolled: N/A

Phase 2/Qualitative subjects enrollment duration will be approximately 12 months.

8.3. Estimated date for the investigators to complete this study:

12/01/2028

9. Study Population[20]

9.1. Inclusion criteria for each subject population (e.g., patients, parents, providers):

Phase 1 PWG participation, including process evaluation focus groups and interviews:

1. Parent/caregivers/LAR/guardians members of the PWG (or the "Parent Expert Panel") (n=24):
   - Parent, caregiver, LAR, or guardian of a child who has received care at NCH-PN
   - Identifies as Black or African American
2. Coach members of the PWG (n=12):
   - Health Coach employed at one of the participating NCH-PCNs
3. Staff and Provider members of the PWG (n=36):
   - Provider or staff employed at one of the participating NCH-PCNs
4. NCH-PCN Coach Coordinator (n=2)

Coach Coordinator employed at NCH-PCNs

Phase 2 Quantitative De-identified chart and administrative data only:

- Age ≥9 and≤15 months on day of data collection
- ≥1 visit at the practice in previous 9 months

- Continuously insured by the ACO in previous 9 months
- Parent/caregivers/LAR/guardians of child whose data is included

Phase 2 Qualitative Interview Data:

- Parent/caregivers/LAR/guardians of child who has experienced adapted PARENT
- Parent/caregivers/LAR/guardians of child who identifies as Black or African American
- Is the primary Parent/caregivers/LAR/guardians who has taken the child WCC visits

Phase 2 Qualitative (chart review): Child who has experienced adapted PARENT and identifies as Black or African American.

9.2. Exclusion criteria for each subject population:

Phase 1 PWG: none
Phase 2 Quantitative/Data only: none

Phase 2 Qualitative/Interview:

- Younger than 21 years old
- Parent/caregivers/LAR/guardians member of the PWG (or "Parent Expert Panel")

9.2.1. If individuals will be excluded from the research based on language, socioeconomic status, physical characteristics (e.g., gender identity, age, ethnicity), sexual orientation, religion, or access to technology provide a justification for each exclusion criterion:[21]

In Phase 1, we are including Parent/caregivers/LAR/guardians members of the PWG (or "Parent Expert Panel") who are Black or African-American because the purpose of this study is to adapt a model of PARENT that is specifically designed to meet the needs of Black children and families. Similarly, in Phase 2, we are including Parent/caregivers/LAR/guardians of children who identify as Black or African-American to participate in the qualitative interview because one of the study aim's is to understand this populations experiences of receiving the adapted PARENT model.

We will not be including language as an inclusion criterion.

9.3. Plan to ensure that subject selection is equitable:[22]
This study is specifically designed to meet the specific needs of Black families.

9.4. Populations with special considerations, involved in the study:[23]

☒ Children/Teenagers[24]
Risk assessment specific to this vulnerable population and additional safeguards:[25]
Child participants are not directly involved in the study (only Phase 2 Qualitative chart review to understand engagement levels with PARENT coaches) so this is no greater than minimal risk to them.

☐ Children who are Wards of the State[26]
Risk assessment specific to this vulnerable population and additional safeguards:
N/A

☐ Adults Unable to Consent [27]
Risk assessment specific to this vulnerable population and additional safeguards:

N/A

☒ Individuals who use a language other than English[28]
Anticipated language(s) for subjects and their parent(s)/LAR:
Spanish

Process to ensure study information is available throughout the research to individuals who use a language other than English:[29]
All study materials will be translated into Spanish and the study will include Spanish speaking staff whenever possible. If needed interpreters will be utilized.

☐ Neonates of Uncertain Viability or Non–Viable Neonates[30]
Risk assessment specific to this vulnerable population and additional safeguards:
N/A

☐ Pregnant Women[31]
Additional safeguards:
N/A

☐ Prisoners[32]
Additional safeguards:
N/A

☒ Economically or educationally disadvantaged persons[33]
Additional safeguards:
All study staff for this project are specifically experienced and knowledgeable of inequities in healthcare and research and are particularly suited to ensure there is no coercion or undo influence. Additionally, the following safeguards aid to minimize coercion or undue influence. (1) The recruitment process has been designed to ensure participation is voluntary. (2) Recruitment materials do not promise “free” services or treatment, nor do they emphasize direct benefit to the participating subject during the research. (3) Incentive for research participation is commensurate with the risk, discomfort, and inconvenience involved in research, and financial or gains are not overly compelling. (4) Study materials have been designed for the possibility of limited reading skills. (6) Participant will be reminded of their rights as a participant to ensure open and free communication between researcher and the prospective subject. The minimal risk status of this study does not indicate the need for additional safeguards for these populations.

10. Number of Subjects

10.1. Total number of subjects to be enrolled locally:[34]
Phase 1: 0
Phase 2 Quantitative:0
Phase 2 Qualitative: 0

10.2. Total number of subjects to be enrolled across all participating sites:[35]
Phase 1 PWG meetings and process evaluation focus groups and interviews :12 (Coach PWG Members)

- 24 (Parent/caregivers/LAR/guardians PWG Members)

- 36 (Provider and staff PWG Members)
- 2 (Coach Coordinator)

Phase 2 Quantitative: 13,980
Phase 2 Qualitative: 72 (parent-child participants)

10.3. Number of screened subjects versus the actual number enrolled in the research:[36]
N/A

10.4. Power analysis:
Quantitative: We have ≥ 80% power to detect primary outcomes based on NCH-PCN data of currently eligible patients in the practice sites, and previous trial data. Estimates assume practice-level ICCs of 0.02-0.05 based on prior studies,80,81 alpha ≤ 0.05, and 233 eligible patients per practice (12 practices total) at each of 5 measurement periods (total 13,980).

Qualitative: We anticipate interviewing 3 Parent/caregivers/LAR/guardians per practice site (n=36) to achieve data sufficiency but will adapt based on preliminary data analysis conducted with ongoing data collection.

11. Withdrawal of Subjects

11.1. Anticipated circumstances under which subjects will be withdrawn from the research without their consent:

Parent/caregivers/LAR/guardians members of the PWG may be withdrawn from the study without their consent if they download or access illicit materials using study-provided tablets.

11.2. Procedures for orderly termination:
The study team will reach out to the parent/caregivers/LAR/guardians to retrieve the tablet upon learning that they have downloaded or accessed any illicit materials on study-provided tablets.

11.3. Procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection and withdrawal from data/biospecimen banking:
If a participant in Phase 1 chooses to withdraw from the study or is withdrawn by the study team, the research team will recruit a replacement PWG member. Upon request, we will redact/remove any individual-level feedback or contribution they provided from PWG meetings and Process Evaluation focus group or interview notes and recordings.
If a participant in the qualitative interview requests to be withdrawn from the study prior to analysis, their interview will be discarded at their request and excluded from analysis.

12. Risks to Subjects

12.1. Reasonably foreseeable risks to subjects (include each study population, each arm, and optional procedures):
The overall risks of both phases of the research plan are minimal. There are no apparent physical, economic, or legal risks associated with the research. Those who receive the PARENT model may experience some inconvenience due to the extended length of their well-child visits. Potential risk of breach of confidentiality (Phase 2 chart review) but the risk is minimal, and we have steps to ensure all risks are minimized.

12.2. Procedures with unforeseeable risks:

N/A

12.3. Procedures with risks to an embryo or fetus should the subject be or become pregnant:
N/A

12.4. Risks to others who are not subjects:
N/A

12.5. Procedures performed to lessen the probability or magnitude of risks:
Phase 1: PWG members will only provide their perspectives on how care should be provided at the practice. All data gained from PWG and parent group meetings will be recorded without identifying information for the participant.

Quantitative Phase 2: Families who receive the intervention will receive all national-recommended WCC services and will continue to have a licensed pediatric clinician at every well-visit. The collected data will be pulled from the EHR and ACO and will not require chart review. Chart review requires opening a patient's chart to obtain information. We will not do that. NCH will query the EHR, and appropriate data fields will be populated in a spreadsheet, with patient info de-identified. This is an automated process that does not require opening any chart of any patient. This will protect patients by limiting access to patient information only to the data necessary for research purposes. Collected EHR and ACO data will be protected by ensuring it is transmitted and stored securely. It will never be transmitted by email. A unique identifier will be used to link the EHR to the ACO record. To ensure information is not identifiable we will use the geocode instead of actual addresses to get census level data for each individual. Data will be pulled by individuals associated with the EHR ACO systems, not study staff, and transmitted to the study team without identifying information. Census level data will be determined for each individual but utilizing the geocode instead of individuals' addresses.

All research facilities have secure access. This includes research buildings, cabinets, computers, and shared drives. All research material will be exclusively accessible to study staff, and the study's student volunteer.

We are not collecting any data that could represent potential reportable events or any data that could represent "alarm values". Data will be pulled from the EHR that includes healthcare utilization (WCC visits, sick and urgent care visits, ED visits, and hospitalizations). We will also pull data on whether anticipatory guidance was provided, whether screening and referral services were completed for social needs, development and behavior, and if parents completed the referral process for community referrals. These data are de-identified, and pre-existing in the medical record.

There is, however, a risk of a reportable events or alarm values during the clinical care that families receive, both in the control and intervention conditions. This is part of clinical care, and not an element of the research study, since when practices move from usual care to the intervention, they are changing their way of providing care universally for that age group. Since the coach is employed by NCH-PCN, and part of the clinical team, they will follow the reporting processes for events and alarm values followed by all clinical staff in the clinic setting. The coach will report to their NCH-PCN clinical manager and follow all clinical protocols of NCH-PCN. Dr. Snyder, our NCH-PCN Operational Director for the project, will ensure that the coaches are fully integrated into the clinical protocols and supervised per NCH-PCN clinical standards.

Qualitative Phase 2: All qualitative interviews will be audio and/or video-recorded. Only study personnel will have access to the audio/video recording files and interview transcripts, which will be electronic only, and saved on secure, password-protected files. Trained,

experienced study personnel will be conducting all interviews. The study team will not include or link the names of any participants or any other personal identifying information in any reports or publications of the findings. Subject identifiers will be contained in the audio files and transcripts only. Electronic material will be kept in a password-protected computer in an office in a restricted access research building. At study completion, all audiotapes, video recording, transcripts, and notes will be deleted. For chart review, only approved study team members will only access necessary information from the medical records in a private setting. We will not maintain any information containing subject identifiers after the study is complete.

When Zoom is used, the following actions will be taken to protect confidentiality and privacy:

- The latest version of Zoom will be used
- The meeting will be made private
- A password will be required for meeting entry
- Private chat will be disabled
- Consent will be obtained prior to recording audio and/or video

13. Potential Benefits to Subjects

13.1. Potential benefits that individual subjects may experience from taking part in the research:[37]

We do not expect that participants in Phase 1 will receive direct benefits to themselves. However, participants in the Phase 2 intervention periods will receive WCC services in a manner that was designed specifically to improve the effectiveness and patient-centeredness of care.

14. Data Analysis/Management

14.1. Data analysis plan, including statistical procedures:

Quantitative Analysis. The analysis will incorporate the unique characteristics of the stepped wedge design, including the unidirectional crossover of practices from control to intervention over time and the hierarchical design, with individual patients nested within coaches and practices. By design there is one coach per practice, reducing coach and practice to a single hierarchical level. Eligibility age range ensures that no child will be eligible at more than one time point (eligibility age range < step length), and that each eligible child has at least 3-4 WCC visit opportunities for intervention exposure. Families may have multiple eligible children during the study period, so we will limit to one randomly selected child per family, using the EHR's geo-coded home address to identify children in the same household.

We will examine distributions of outcome variables for each time point, practice, and control/intervention status using summary statistics and graphical tools. We will assess missing data amount and patterns for all outcomes, estimated <1%, based on current EHR missing race data. Multiple imputation will be used to handle missing data as appropriate, and sensitivity analyses to gauge impact of missing data and of multiple imputation. All tests are two-sided; p values <0.05 will be considered statistically significant. We will assess comparability of intervention vs control data by comparing means/frequencies of potential confounding covariates (e.g., child age) using appropriate statistical tests. If groups differ, unbalanced variables will be included as covariates in analyses. Outliers will be investigated by inspecting residuals. Models will be fit with and without outliers to examine their influence on results.

Aim 2: Determine the effect of adapted PARENT on receipt of preventive care services, ED utilization, and parent experiences of care. We hypothesize increased receipt of preventive care services, decreased ED utilization, and better parent experiences of care, for intervention compared to traditional guideline-based preventive care. The unit of analysis will be the individual patient, nested within coach/practice (with one coach per practice). Receipt of each WCC service (yes/no, over the past 9 months) and ED utilization (any/none, over the

past 9 months) will be compared, for control vs intervention. We use “receipt of service” to describe the analytical approach, which will also apply to ED utilization and experiences of care. The rate of receipt of services will be defined as the number of eligible patients who received that service at any time over the past 9 months, divided by the number of eligible patients identified at that time point. We will use t-tests to compare changes in receipt of services at each practice, before and after intervention implementation. As this approach does not account for potential temporal effects, our main analyses will employ mixed effects logistic regression models using data collected at T0-T6, as described below. Individual-level data from administrative records at each time point for each patient, and demographics will be included in a mixed effects logistic regression model. We will assess the receipt of each service (yes/no) individually, and as a composite (all three services received or not).
Our multivariable models will include the following variables unique to each patient – practice – time interval combination: a) binary outcome, b) intervention/control, and c) a binary indicator variable for each time interval. We will include practice-specific random effects that account for within practice correlations, and an error term specific to each participant. We will include patient and practice-level confounding variables, and adjust for potential seasonal effects. The intervention effect is modeled as a fixed effect, while a separate fixed effect for each time point will aim to capture any temporal trend. This approach uses both within-practice and between-practice information to estimate the intervention effect and accounts for varying numbers of data points for control vs intervention across practices and time points. Temporal effects will be assessed by testing whether time point beta coefficients equal zero. Cluster size stratum will also be included as a fixed effect. Finally, we will assess whether intervention effects are sustained over time by using t-tests to compare rates of receipt of services at T6 vs T3-5, for PWGs 1-3 respectively.
For the outcome of ED utilization and parent experiences of care, analyses will be very similar. For ED, we will adjust for season due to its potential effect on ED utilization. We will use ED utilization as dichotomous variable (0 vs 1+ visits). We will also examine the distribution of this variable and will perform and report on sensitivity analyses using alternative parameterizations of this variable (e.g., 0-1 vs. 2+).
Additional sensitivity analyses may be conducted for our primary outcomes (receipt of services, ED utilization, experiences of care) to examine differences across practices, and by provider, though we expect that the coach is the main vehicle for intervention effect on outcomes.

Models will be modified accordingly based on patterns observed in the data (e.g., we may add a random effect for provider if there is evidence of meaningful clustering by provider), and we will assess and appropriately model correlation structure in the data. As practices implementing the intervention later may benefit from the experiences of earlier practices, we will assess possible time-varying intervention effect, and may choose to model time or treatment using random effects. Analyses for our secondary outcomes will use a similar approach as described above. Analyses will be conducted in accordance with the CONSORT guidelines for Stepped Wedge trials.
Aim 3: Determine whether effectiveness of adapted PARENT differs by family-level factors (e.g., race and ethnicity, parent - Coach racial and ethnic concordance). To test our hypothesis (intervention impact will be present and positive for all participants, but greatest for Black families and those with racial and ethnic concordance with the Coach), we will apply a similar statistical approach to the one described for Aim 2, however, we will first limit analyses to each specific sub-population of interest, specifically, family race and ethnicity (Black vs. Latinx vs. White), and parent - coach racial concordance (concordant/discordant). Our analysis plan will allow us to distinguish whether intervention effects for Black families are independent of racial concordance. We estimate 42% parent - coach racial concordance,

based on current coach race and ethnicity estimates and breakdown of current eligible patients. Model specifications will be similar to those described for Aim 2. If intervention effect appears to differ by sub-population, then an interaction term between the variable and intervention will be entered into a model to assess the significance of the interaction and estimate differences in intervention effectiveness across subgroups of interest. Additional characteristics may also be considered as potential effect modifiers, on an exploratory basis. Since parent race is not in the EHR, we will use child race and ethnicity as a proxy, recognizing limitations for multiracial children and children with a non-biological parent.
For Aims 2 and 3, our main analysis will follow Intent-To-Treat, with clusters analyzed according to their randomized crossover timepoint. This analysis may be followed by a secondary, As Treated analysis, depending on variation from intended crossover timepoint and intervention "dose" considerations. We will report all prespecified analyses as well as the number of post-hoc analyses, in terms of subgroups as well as outcomes analyzed.
Overview of Qualitative Analysis. Qualitative data will be analyzed in Dedoose Version 10.0.34 using thematic analysis following the procedures outlined by Braun and Clarke; our approach and reporting will conform to the Standards for Reporting Qualitative Research. We describe our analysis plan for Aim 4 below; this same approach will be applied for analysis of Aim 1's process evaluation (focus group discussions of each PWG's Parent Expert Panel and of Coaches).
Aim 4: Explore parents' experiences in receiving adapted PARENT. Interviews will be recorded and transcribed. A hierarchically-organized codebook will be developed using the following process: initial codes derived from study aims and discussion topics; codes adapted and augmented by a reading of five transcripts; codes tested on two additional transcripts by all coders; discrepancies resolved by discussion; codebook edited as appropriate until an exhaustive but manageable code list is reached. Transcripts will be open-coded using the final version of the codebook. All transcripts will be coded by two coders (blinded to each other's coding), at least one of whom has conducted the interview when possible. All differences will be resolved by discussion until 100% agreement is reached. When necessary, the codebook will be modified to accommodate new codes or definitions and recoding conducted as necessary. Each code report will be synthesized by one analyst using a system of annotating and summarizing into theme domains and subdomains with associated quotes. This full data analysis will occur during Year 5, after all interviews have been completed.
Aim 5. Examine the economic impact of adapted PARENT from the parent stakeholder perspective. The unit of analysis will be the individual patient, nested within coach/practice (with one coach per practice). Total visit time in minutes and time with each team member (pediatric provider, coach, RN/MA) will be compared, for control vs. intervention. Visit and team member time will be defined as the mean number of minutes at each data pull, across all WCC visits for each eligible patient over the past 9 months. We will use t-tests to compare changes in mean time for each practice, before and after intervention implementation. As this approach does not account for potential temporal effects, our main analyses will employ mixed effects linear regression models using data collected at T0/T2-T6, as described below. Individual-level data from administrative records at each time point for each patient, and demographics will be included in a mixed effects linear regression model.
Our multivariable models will include the following variables unique to each patient – practice – time interval combination: a) binary outcome, b) intervention/control, and c) a binary indicator variable for each time interval. We will include practice-specific random effects that account for within practice correlations, and an error term specific to each participant. We will include patient and practice-level confounding variables, and adjust for potential seasonal effects. The intervention effect is modeled as a fixed effect, while a separate fixed effect for each time point will aim to capture any temporal trend. This approach uses both within-practice and between-practice information to estimate the intervention effect and accounts for varying numbers of data points for control vs. intervention across practices and time points.

Temporal effects will be assessed by testing whether time point beta coefficients equal zero. Cluster size stratum will also be included as a fixed effect. Finally, we will assess whether intervention effects are sustained over time by using t-tests to compare mean visit and team member time at T6 vs T3-T5, for wedges 1-3 respectively.

Aim 6. Examine the economic impact of adapted PARENT from the pediatric provider and clinic stakeholder perspective. Analysis for Aim 6 will be similar to that of Aim 5. We will use the method above, but focused on the outcomes of mean provider-parent time, and mean provider EHR time for each WCC visit, for intervention and control.

Aim 7. Examine the economic impact of adapted PARENT on healthcare utilization, from the perspectives of parents and families. This analysis will utilize the data collection and power analysis for healthcare utilization described in Aims 2-3. We will estimate differences in patient-focused costs of this utilization using the methods described for Aims 5 and 6 above. We will assign estimated out-of-pocket cost and time for travel to the ED, urgent care, or hospital visit location (using geocoded data that indicates home address as well as location of care), using software (e.g., ArcGIS) and statistical packages to calculate driving travel time and cost, as well as public transportation time and cost, for round trip between the two geocoded locations (home and healthcare site). Missed work time will be calculated using census tract data on median household income. We will also investigate and pilot additional methods for estimating public transit time. If we do not find a significant difference in utilization between intervention and control (under Aim 2), we will still complete Aim 7 to quantify these out-of-pocket costs to utilization, which can inform patient-centered costs of healthcare utilization in early childhood.

Sample Size and Power: We have ≥ 80% power to detect primary outcomes described within Aims 2, 3, 5, and 6 based on NCH-PCN data of currently eligible patients in the practice sites, and previous trial data. Estimates for Aims 2-3 assume practice-level ICCs of 0.02-0.05 based on prior studies,82,83 alpha ≤ 0.05, and 233 eligible patients per practice (12 practices total) at each of 5 measurement periods (total 13,980). Calculations were based on the harmonic mean of eligible patients per clinic (233), and not the arithmetic mean (300), as the latter can result in inflated power estimates if cluster sizes vary. We also have ≥80% power for subgroup analyses by race and by parent–coach racial concordance for Black families. We will have ≥80% power to detect these same differences in ED use and social needs screening among Latinx and White subgroups. Estimates for Aims 5-6 assume practice-level ICCs of 0.01-0.30 (we utilize a range since there are no data on ICC estimates for this analysis), using an alpha ≤ 0.05. For Aims 5-7, we will have data from all data collections or “measurement periods”, which total 13, 980 patients, or 233 eligible patients per practice (12 practices total) at each of the 5 measurement periods per cluster. Although the start date for the PCEO Aims 5-7 will occur after our first two data collection periods (T0 and T1), we will retroactively pull data for total visit time, provider-parent time, RN/MA -parent time, and EHR time for provider from the same T0 and T1 time periods, as these time-stamped data are pre-existing in the EHR. The coach-parent time outcome will require EHR building in Year 2 of the project. Coach-parent time will be zero during the control period, which is pre-intervention. Power for Aim 7 mirrors power for the healthcare utilization aim within the study, as it will be based on differences in utilization, and has the same N (13,980). Aims 5-7 do not include any subgroup analyses. See Table 3.

Qualitative sample size was determined based on number of practice sites. We will purposefully recruit participants from each site and later assess level of engagement. We anticipate interviewing 3 Parent/caregivers/LAR/guardians per practice site (n=36) to achieve data sufficiency but will adapt based on preliminary data analysis conducted with ongoing data collection.

Table 3. Primary, Secondary, Supplemental Outcomes (*Secondary outcomes described above, under Measures)*					**Table 7b. Statistical Power**			
Name of Outcome	**Specific measure to be used** [*pilot RCT estimates in Table 1, control vs. intervention*] {PCEO Aims, Minimal difference, control vs intervention}	**Time points**	**Powered ?**	**Base line**	**Aims 2 and 7**	**Aim 3: Subgroup Analyses**		**Aims 5 and 6**
						Black (~50%)	Concordant ‡ (~42%)	
Receipt of Preventive Care Services (n=13,980 patients)	Anticipatory guidance [77% vs. 89%] Social needs screening [78% vs. 95%] Developmental screening [81% vs. 92%]	Every 9 months, 5 timepoints	Yes	--	>99% >99% >99%	90-92% >99% 89-91%	85-88% 99% 84-87%	--
Healthcare Utilization (n=13,980 patients)	Emergency department visits [35% vs. 18%]	same	Yes	--	>99%	98-99%	96-97%	--
Experiences of Care (n=13,980 patients)	Family-Centeredness [mean (SD): 92(13) vs. 96 (8)]	same	Yes	--	>99%	97-98%	86-90%	--
Total visit time (n=13,980 patients)	Time stamped; minutes parent spends in well- visit, from check in to discharge {4.06-4.16 minutes}	same	Yes	71 minutes [1]	--	--	--	≥80%
Provider-parent time (n=13,980 patients)	Time stamped; minutes provider (i.e., pediatrician) spends with parent during visit {0.44-0.46 minutes}	same	Yes	14 minutes [1]	--	--	--	≥80%
Coach-parent time (n=6,671 patients)	Time stamped; minutes coach spends with parent during visit (intervention period only) {n/a (intervention only)}	Every 9 months, 3 timepoints	Yes	15 minutes [2]	--	--	--	≥80%
RN/MA time (n=13,980 patients)	Time stamped; minutes for RN/MA portion of well-visit {0.35-0.36 minutes}	same	Yes	8 minutes [1]	--	--	--	≥80%
EHR time for provider (n= 13,980 patients)	Time stamped; minutes from opening to closing chart for each well-visit {0.72-0.74 minutes}	same	Yes	12 minutes [3]	--	--	--	≥80%

‡ *Racial concordance/discordance of parent-coach based on current NCH-PCN staff & patient data*

[1]50th percentile, from Liljenquist et al 2023; [2]Based on previous PARENT RCT; [3]From Overhage & McCallie, Pediatrician Electronic Health Record Time Use for Outpatient Encounters. Pediatrics. Dec 2020

14.2. Quality control procedures for collected data:[38]

NCH-PCN and the ACO have full capability in detailed data queries, and currently can complete data pulls on all of our primary outcomes and the majority of secondary outcomes. The IT team will complete programming for the final secondary outcomes prior to study start. Finally, EHR data is already geo-coded, using patient home address. NCH-PCN uses tablet-based methods for collection of parent-reported data and measures, and these data are automatically uploaded to the EHR. NCH-PCN will use their current tablet-based parent reported measurement system for the study. In addition to their tablet-based parent reported measurement system, NCH-PCN will also utilize MyChart delivered surveys to collect Anticipatory Guidance and Parent Experiences of Care data and measures.

15. Confidentiality and Privacy[39]

15.1. Procedures to secure research records[40], data, and/or biospecimens during storage, use, and transmission:

Phase 1:

For the Phase 1 PWG, the only data collected will be recorded without identifying information. Data that is collected will be done so on secure platforms, such as Zoom Enterprise, Microsoft Teams and SCRI's OneDrive, only accessible to research staff,the study's student volunteers, and/or external collaborators.

Phase 2

All data will be stored in locked cabinets in locked research offices and/or secure computer files. No presentation or publication arising from this research will use subject names or other information that would allow subjects to be identified. Furthermore, the study team will comply with SCRI's Research Data Management Policy, which outlines that:

- All research data must be securely stored on a researcher's "Active" and "Archive" file shares.
- Data must be backed up regularly
- Any files stored on a desktop PC or removable media must be encrypted.
- Data access permission must be kept up to date.

All clinical and administrative data (EHR and ACO data) transmitted from NCH to SCRI for 9-month data pulls, monthly fidelity, and phase 2 qualitative chart review will be transmitted using a SCRI secure File Transport Protocol (FTP) platform. When data is transferred through the FTP, all files will be encrypted and password-protected and uploaded into a secure file share managed by SCRI. Only Dr. Coker, Dr. Ellyson, the SCRI Research Manager, the SCRI Biostatistician, and the SCRI Clinical Research Assistants/Associates will have access to this file share.

15.2. Steps that will be taken to protect the privacy interests throughout the study:[41]

Data in the Phase 1 PWG and the Phase 2 Quantitative activities will be stored without identifiable information; therefore no private information may be connected to any individual.

Phase 2 Qualitative participants will first be identified by their Coach and approached to participate in the study. Trained, experienced study personnel will be conducting all interviews. The study team will not include or link the names of any participants or any other personal identifying information in any reports or publications of the findings. Subject identifiers will be contained in the audio/video recording files and transcripts only. Study personnel will have access to the audio/video recording files and interview transcripts, which will be electronic only, and saved on secure, password-protected files. De-identified data will be accessible to external collaborators. Electronic material will be kept in a password-protected computer in an office in a restricted access research building. At study completion, all audiotapes, video recording, transcripts, and notes will be deleted. We will not maintain any information containing subject identifiers after the study is complete.

15.3. Location where the data and/or biospecimens will be stored:

Data will be stored locally on study specific shared drives on the Seattle Children's server and Seattle Children's Microsoft Teams.

15.4. Length of time data and/or biospecimens will be stored:

Deidentified data will be stored indefinitely. Any identifiable data such as interview recordings and transcripts will be destroyed after analysis is complete.

15.5. Individuals with access to data and/or biospecimens:
Only study staff, or the study's student volunteer, will have access to the study data. De-identified data will be accessible to external collaborators.

15.6. Process for the transmission of data and/or biospecimens outside Seattle Children's:
15.6.1. List of data and/or biospecimens that will be transmitted:
Data that is transferred between Seattle Children's and NCH will be done so via a secure FTP and/or SCRI's Microsoft Teams Channel dedicated to the study and study staff at both sites.

15.6.2. Individual(s) who will transmit data:
Only qualified research staff will transmit data outside of Seattle Children's.

16. Provisions to Monitor Data to Ensure the Safety of Subjects[42]

16.1. Plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe:[43]

16.2. Data reviewed to ensure safety of subjects:
N/A

16.3. Safety information collection procedures:
N/A

16.4. Frequency of cumulative data review:
N/A

16.5. Conditions that trigger an immediate suspension of the research:
N/A

17. Use of Social Media

17.1. Types of social media to be used and how:
N/A

17.2. Measures in place to protect the privacy or confidentiality of subjects:[44]
✍Click here to enter text.

17.3. Types of communications that will be submitted to the IRB for review:[45]
✍Click here to enter text.

17.4. If user-generated content will be active, how it will be monitored and what actions will be taken to ensure subject safety and study integrity:
✍Click here to enter text.

18. Research Related Injury[46]

18.1. Available compensation in the event of research related injury:
N/A

19. Recruitment Methods[47]

19.1. When, where, and how potential subjects will be recruited[48]:

PWG: NCH-PCN staff and providers will be recruited by the Medical Director via email and/or in person conversation. Parent/caregiver/LAR/guardian members will be recruited via email, phone call and/or in person conversation. NCH-PCN study team members will screen the EHR to identify parents/caregivers/LAR/guardians who meet study eligibility criteria and ask NCH-PCN staff and providers, either in-person or via secure Email or Epic Secure Chat, to talk with the parent/caregivers/LAR/guardians during an upcoming WCC visit to determine if they are interested in learning about the study. If individuals indicate they are interested, communication in the form of approved recruitment materials will be sent in-person or by phone (in a private setting), or via secure email by the study team.
Parents/caregivers/LAR/guardians may also be contacted by someone from the clinic who they already know, at which time they will be provided with a brief overview of the PWG and asked if their information can be shared with the study team so they may be contacted to learn more. A study recruitment flyer will be posted in NCH-PCN participating clinic sites in order to recruit potential parent/caregiver/LAR/guardian PWG members. In addition to these methods, the study team will also enroll eligible parent/caregiver/LAR/guardian PWG members who hear about the study via word of mouth from other parent/caregiver/LAR/guardian participants who were approached by the study or who had access to the flyer.

Phase 2 Quantitative: N/A

Phase 2 Qualitative: Parent coaches will ask potentially eligible participants if they are interested in participating in the study. This outreach will be done in-person, during the patient's return WCC visit. They will be provided the study flyer. For individuals who are interested in being contacted by the study team to learn more, the Coaches will instruct patients to scan a QR code on the flyer, where they will enter their contact information. The contact information will be captured on a form only accessible by NCH Study team and Coaches. The NCH Coordinator will reach out to parents who enter contact information in this form and setup a phone meeting to discuss the study more and obtain verbal consent. Whenever possible, the research staff will provide these individuals with a copy of the consent form to review before meeting so they have time to formulate any questions they may have.

19.2. Steps that will be taken to protect privacy during the recruitment process:[49]
PWG: Potential participant information will be maintained in secure documents on secure networks. Names and contact information will be shared via secure email, Epic Secure Chat, or Microsoft Teams. Epic Secure Chat will only be used for communication between study staff and clinicians/providers. This is a function that is in use for non-research purposes for communication by providers and staff at NCH by way of an approved institution wide application used at this site. It will be used in its typical indication for recruitment purposes.

Phase 2 Quantitative: N/A

Phase 2 Qualitative: Recruitment conversations will occur in the privacy of the typical Coach sessions. Contact information will be shared with research staff only via secure communications and will not include additional clinical or private information. Research staff will conduct recruitment calls and conversations in private settings and ensure potential participants have the appropriate privacy in their locations at the start of each recruitment conversation.

19.3. Sources of subjects:[50]

PWG: Nominated by NCH-PCN clinic staff and providers. Parent/caregiver/LAR/guardian PWG members will also be recruited via study recruitment flyer that will be posted in participating NCH-PCN clinic sites.

Phase 2 Quantitative: Electronic Medical Records

Phase 2 Qualitative: Patients who work with the Coaches and are nominated by the Coaches

19.4. Methods that will be used to identify potential subjects:

PWG: PWG will be identified by the clinic providers and staff. Parent/caregiver/LAR/guardian PWG members will also be identified by screening the NCH-PCN EHR and via recruitment flyer that will be posted in participating NCH-PCN sites.

Phase 2 Quantitative: N/A

Phase 2 Qualitative: Coaches will identify parents they work with as potential interview participants.). The Coach will provide the recruitment flyer with a QR code to a contact form in which the parent will provide their permission to be contacted by research staff and contact information.

19.5. Materials that will be used to recruit subjects:[51]

PWG: E-mail and other material, including a recruitment flyer.
Phase 2 Quantitative: N/A
Phase 2 Qualitative: Recruitment flyer and NCH coordinator's outreach scripts

19.6. Recruitment methods not controlled by Seattle Children's:

N/A

20. Consent/Assent/Permission[52]

20.1. Consent/assent/permission process:[53]

Phase 1 PWG (Meetings): Potential PWG members (n=72) will be provided with an information sheet during the recruitment process. Verbal consent will be obtained prior to engaging in the PWG procedures, including Parent Expert Panel, PWG meetings and Process Evaluation focus groups and interviews.

Phase 1 PWG (Process Evaluation focus groups and interviews):
Parent/caregiver/LAR/guardian (n=24) and Coach (n=12) and Staff and Provider (n=36) participants of the PWG, as well as the NCH-PCN Coach Coordinator (n=2)will be provided with an information sheet during the recruitment and initiation processes. Verbal consent will be obtained prior to contributing to Process Evaluation focus groups or interviews.

Phase 2 Quantitative: Participants (n=13,980) in this group will not be consented. For Phase 2 Quantitative activities, we are requesting a waiver of consent/assent because we will have no direct contact nor will we be engaged directly in any other research procedures. Although the collection of data is planned prospectively, the actual extraction of the data from the EHR and ACO administrative data will always take place in a retrospective manner, such that the data would already be in "existence" in the medical records and administrative data, and would have been collected for clinical purposes, and not specifically for this research proposal.

Phase 2 Qualitative: Participants (n=36) in this group will be provided with a copy of the information sheet form during the recruitment process by the Coach or a Study team member

and/or via email or text while communicating to schedule a time to talk about the study in detail. Verbal consent will be obtained by NCH study team over the phone or video conference prior to starting research procedures. As for the chart review, we are requesting a waiver of assent because (1) the participants are infants who lack the developmental capacity to provide assent; (2) the research involves minimal risk; (3) parental permission will still be obtained verbally prior to chart review; (4) identifiable chart information must be accessed to determine eligibility and engagement history, but no PHI will be stored as part of the research dataset; and (5) the waiver will not adversely affect the rights or welfare of the child. Requiring assent in this population would not be practicable and would not provide additional protection.
See Table 4 for an outline of the 5 information sheets and associated research subject groups and activities.

Table 4: Information Sheets by Activity and Research Subject Group

20.1.1. Alternative way of obtaining consent/assent/permission information for individuals who are not able to receive/access/use the electronic consent system being used or explanation as to why an alternative process is unnecessary:[54]
N/A

20.1.2. Where the consent/assent/permission process will take place:
Phase 1 PWG: This will occur in person, over the phone, or via video conferencing (WebEx, TEAMs or Zoom Enterprise) at the preference of the participant.

Information Sheet	Phase	Activity	Research Subject Group (n)
1. Information Sheet for PWG Parent Expert Panel and Process Evaluation	1	-Participation in PWG -Contribution to Process Evaluation focus group	Parent caregivers/LAR/guardians members of the PWG (or members of the "Parent Expert Panel) **(n= 24)**
2. Information Sheet for Coach Members of the PWG and Process Evaluation	1	-Participation in PWG -Contribution to Process Evaluation interview	Coach members of the PWG **(n=12)**
3.Information Sheet for Providers and Staff Members of the PWG	1	-Participation in PWG -Contribution to Process Evaluation focus group	Provider and Staff members of the PWG **(n=36)**
4. Information Sheet for Coach Coordinator	1	-Contribution to Process Evaluation interview	Coach Coordinator **(n=2)**
5. Information Sheet for Qualitative Interviews	2	Qualitative Interviews	Parent/caregivers/LAR/guardians of Children and their child who experienced adapted PARENT model **(n=72)**

Phase 2 Qualitative: This will occur over the phone, or via video conferencing via WebEx, TEAMs, or Zoom Enterprise.

20.1.3. Steps that will be taken to protect privacy during the consent/assent/permission process:[55]
Whenever in-person consent will be done, it will be conducted in a private room with assured privacy. Whenever done over the phone or video conferencing, study staff will do so in private spaces and ask participants if they have reasonable privacy where they are.

20.2. Plan for documenting consent/assent/permission:[56]
PWG: Consent will not be documented by the study participant but may be tracked administratively on study master logs.

Phase 2 Qualitative: Consent will not be documented by the study participant's signature, but may be tracked administratively on study master logs.

20.2.1. Plan to confirm that the individual who provides the electronic signature[57] is the subject (or their parent/LAR), when the signature is not personally witnessed by a member of the study team or explanation as to why such a plan is unnecessary:[58]
N/A

20.2.2. If using electronic consent, plan to manage consent documentation over the life of the study in a way that maintains integrity and accessibility:[59]
N/A

20.2.3. If consent/permission will be documented in writing (check one):
☒ "SOP: Written Documentation of Consent (HRP-091)" will be followed.
☐ "SOP: Written Documentation of Consent (HRP-091)" will not be followed.
Process of documenting consent:[60]
✍Click here to enter text.

20.2.4. If consent/permission will not be documented in writing (check all that apply, *complete Section 21.11 to request a Waiver of Documentation of Consent*)[61]
☒ A written statement/information sheet describing the research will be provided to subjects.[62]
☐ A written statement/information sheet describing the research will not be provided to subjects. Explain: ✍Click here to enter text.
☐ A consent script will be used.[63]

20.3. Waiting period available between approach and obtaining consent/assent/permission:
All potential participants will be provided with a copy of the information sheet days to weeks prior to conducting the consent conference.

20.4. Process to ensure ongoing consent/assent/permission:
All study participants will be reminded throughout the study that their participation is voluntary and they may withdraw at any time. We will inform them of changes to relevant study procedures as they may occur.

20.5. If this box is checked, "SOP: Informed Consent Process for Research (HRP-090)" will be followed: ☒

20.6. If "SOP: Informed Consent Process for Research (HRP-090)" will not be followed, address the following:[64]

20.6.1. Role of the individuals listed in the application as being involved in the consent process:
✍Click here to enter text.

20.6.2. Time that will be devoted to the consent discussion:
✍Click here to enter text.

20.6.3. Steps that will be taken to minimize the possibility of coercion or undue influence:
✍Click here to enter text.

20.6.4. Steps that will be taken to ensure the subject's understanding:
✍Click here to enter text.

20.7. **Individuals who use a language other than English**

20.7.1. Presentation of Research Information and Documentation:

☒ Appendix A-10 of the Investigator Manual will be followed[65]

☐ Short form procedures may be used per HRP-091. If so, choose applicable box(es):

☐ Per section 5.5.1

☐ Per section 5.5.2

☐ Appendix A-10 of the Investigator Manual will not be followed. Explanation of procedures not following Appendix A-10:
✍Click here to enter text.

20.8. **Subjects Who Are Not Yet Adults (Infants, Children, Teenagers)**

20.8.1. Process used to determine whether an individual has not attained the legal age of consent under the applicable law of the jurisdiction in which the research will be conducted (e.g., individuals under the age of 18 years):[66]

For the Phase 2 Quantitative participants, we will extract EHR and ACO data on children ≥ 9 months to 15 months of age at the NCH-PCNs. Applicable laws in Columbus, Ohio, where the research will be conducted, outline that children of this age have not reached the legal age of consent. We will not obtain assent from parents of this population because neither the SCRI or NCH research teams will have direct contact with all of the children (n=13,980 children's records) in which we will pull EHR and ACO data on. For Phase 2 Qualitative, we will check the child's medical records to confirm that the child subject is under the legal age of consent and requires parental permission.

20.8.2. Permission will be obtained from:[67]

☐ Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, or LAR.

☒ One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child, or LAR.
☒ Permission will not be obtained.[68]

20.8.3. Process used to ensure permission is obtained from an individual or individuals (when two parent permission is required) with legal authority to provide such permission::[69]
For Phase 2 Qualitative, we will check the medical records to confirm.

20.8.4. Assent will be obtained from:[70]
☐ All children.
☐ Some children. Specify: ✍Click here to enter text.
☒ None of the children. Explain: Children included in the Phase 2 quantitative/qualitative activities are too young to assent.

20.8.5. Procedures for obtaining and documenting assent:
N/A

20.8.6. Plan for re-approaching children who have reached the age of majority to obtain consent:[71]
Participants will not turn 18 during active participation in the study and data collected is de-identified.

20.9. **Cognitively Impaired Adults/Adults Unable to Consent**[72]

20.9.1. Process used to determine whether an individual is capable of consent:
N/A

20.9.2. Individuals from whom permission will be obtained in order of priority:[73]
✍Click here to enter text.

20.9.3. Assent will be obtained from:
☐ All of these subjects.
☐ Some of these subjects. Specify: ✍Click here to enter text.
☐ None of these subjects. Explain: ✍Click here to enter text.

20.9.4. Process for obtaining and documenting assent:[74]
✍Click here to enter text.

20.10. **Waiver or Alteration of Consent/Assent/Permission**[75]

20.10.1. Reasons for requesting a waiver or alteration of informed consent/assent/permission:[76]
For the Phase 2 Quantitative participants (control and intervention groups), the research team will have no direct contact with the parents or patient participants, so waivers are being requested. Although the collection of data is planned prospectively, the actual extraction of the data from the EHR and ACO administrative data will always take place in a retrospective manner, such that the data would already be in “existence” in the medical records and administrative data,

and would have been collected for clinical purposes, and not specifically for this research proposal.

For Phase 2 Qualitative participants, a waiver of assent is being requested because (1) the participants are infants who lack the developmental capacity to provide assent; (2) the research involves minimal risk; (3) parental permission will still be obtained verbally prior to chart review; (4) identifiable chart information must be accessed to determine eligibility and engagement history, but no PHI will be stored as part of the research dataset; and (5) the waiver will not adversely affect the rights or welfare of the child. Requiring assent in this population would not be practicable and would not provide additional protection.

20.10.2. Consent/Assent Waiver/Alteration Criteria justifications:[77]

20.10.2.1. The research involves no more than minimal risk to the subjects because:

Phase 2 Quantitative: We are only collecting medical record information which will be provided from a retrospective data pull. Additionally, the data that will be collected by research staff will not be individually identifiable.
Phase 2 Qualitative: We are only collecting the minimally necessary chart information, from past visits, in order to determine engagement levels.

20.10.2.2. The waiver or alteration will not adversely affect the rights or welfare of the subjects because:[78]

Data collected is not individually identifiable. We are not collecting any information that would alter the subjects' care or that could put subjects and their families at harm.

20.10.2.3. The research could not practicably be carried out without the waiver or alteration because:[79]

Phase 2 Quantitative: We have no direct contact with these individuals. Neither the SCRI nor NCH research study team members will have direct contact with the parents of the 13,980 children whose records we plan to include in this portion of the study. The parent coaches will of course see patients, but they only see patients during the intervention period, and the clinics are implementing the intervention as part of their own clinical practice.

Phase 2 Qualitative (waiver of assent): Participants are infants who lack the developmental capacity to provide assent. We will obtain verbal parental permission.

20.10.2.4. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format because:[80]

Phase 2 Qualitative (waiver of assent): Identifiable chart information must be accessed to determine past engagement history.

20.10.2.5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation:
N/A

20.10.3. If the research involves a waiver of the consent process for emergency research, provide sufficient information for the IRB to make it determinations:[81]
N/A

20.11. **Waiver of Written Documentation of Consent/Permission (address one option):**

20.11.1. Option 1:

- The research involves no more than minimal risk to the subjects because:
  PWG: Participation in the PWG does not involve collection of any PII or PHI. Information provided is only for the purposes of providing their perspectives on how care should be provided at the practice. All data gained from PWG, parent group meetings, and Process Evaluation focus groups and interviews will be recorded without identifying information for the participant.
- Qualitative Interviews: The only risk to participants is breach of confidentiality. PHI that is collected on these participants will be incidental due to the nature of qualitative interviews and not intentional collected for data purposes. Review of patient's charts to understand engagement levels will require study staff to access the EHR.
- The research involves no procedures for which written consent is normally required outside of the research context because:
  Written consent is not normally required for participating in a PWG or qualitative interview/focus group/chart review.

20.11.2. Option 2:

- The principle risk of a signed consent document would be the potential harm resulting from a breach of confidentiality because:
  ✍Click here to enter text.
- Both are true:
  ☐ The only record linking the subject and the research would be the consent document
  ☐ The subject or LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

20.11.3. Option 3:

- The research involves no more than minimal risk to the subjects because:
  ✍Click here to enter text.
- The subjects or LARs are members of a distinct cultural group or community in which signing forms is not the norm. Explain:
  ✍Click here to enter text.
- There is an appropriate alternative mechanism for documenting that informed consent was obtained. Explain:
  ✍Click here to enter text.

21. HIPAA Authorization and RCW Criteria

21.1. HIPAA Authorization (check all boxes that apply):

☐ The study does not involve the receipt, creation, use and/or disclosure of protected health information (PHI).[82]

☐ HIPAA authorization will be obtained as part of a signed consent form.

☒ The study will access PHI without prior authorization from subjects (including for recruitment purposes – e.g., reviewing the medical record to determine eligibility). *Complete Section 21.2 to request Waiver of HIPAA Authorization*.
☒ Subjects will review a written statement/information sheet with the appropriate HIPAA language but will not provide a written signature. *Complete Section 21.2 below to request an Alteration of HIPAA Authorization*.[83]
☐ Other. Explain:[84]
✍Click here to enter text.

21.2. HIPAA Waiver/Alteration Criteria: [85]

21.2.1. Reasons for requesting a waiver or alteration of HIPAA Authorization:
We currently have a waiver of HIPAA Authorization for Phase 2, we are now requesting a waiver of HIPAA Authorization for Phase 1 so that we can access PHI to identify eligible parents/ caregivers/LAR/guardians for the PWG. For the purpose of payment, the research team may need to collect the names and/or SSN of PWG participants.

Phase 2 Quantitative and Fidelity Review (control and intervention groups): The data pull cannot be accomplished if HIPAA authorization is required.

Phase 2 Qualitative (screening): PHI will be used to identify eligible Parent/caregivers/LAR/guardians whose child was seen by a parent coach.

Alteration of HIPAA authorization (signature requirement) for Phase 2 Qualitative: We are requesting an alteration of HIPAA authorization to remove signature requirement.

21.2.2. The use or disclosure of PHI involves no more than a minimal risk to privacy of individuals, based on, at least the presence of the following elements:

21.2.2.1. An adequate plan to protect the identifiers from improper use and disclosure:

PWG: PHI will only be accessed by NCH-PCN study staff authorized (by local IRB) to access the EHR for screening and recruitment purposes. PHI will not be collected or stored as part of the research dataset.
Phase 2 Quantitative and Fidelity Review (control and intervention groups): PHI will only be accessed through the EHR by NCH-PCN study staff for fidelity data extraction. PHI will not be collected or stored as part of the research dataset.
Phase 2 Qualitative (screening): PHI will only be accessed to screen for eligibility. Such PHI will not be collected or stored as part of the research dataset.
Alteration of HIPAA authorization (signature requirement) for Phase 2 Qualitative: We have appropriate measures to store collected PHI and protect from improper use.

21.2.2.2. An adequate plan to destroy identifiers at earliest opportunity consistent with conduct of research:

Refer to Section 16 above.

21.2.2.3. Assurances that PHI will not be reused or disclosed to any other party or entity, except as required by law or for authorized oversight of the research:

PHI will not be reused or disclosed to any other party or entity, except as required by law or for authorized oversight of the research

21.2.3. The research could not practicably be conducted without the waiver or alteration of authorization:

Waiver of HIPAA Authorization for Recruitment: The use of PHI prior to authorization is necessary to identify eligible participants.

Phase 2 Quantitative and Fidelity Review (control and intervention groups): We have no direct contact with these individuals. Neither the SCRI nor NCH research study team members will have direct contact with the parents of the 13,980 children whose records we plan to include in the quantitative portion of the study. The parent coaches will of course see patients, but they only see patients during the intervention period, and the clinics are implementing the intervention as part of their own clinical practice

Phase 2 Qualitative (screening): The research could not practicably be conducted without the waiver as NCH study team needs to access the EMR to confirm eligibility for recruitment.

Alteration of HIPAA authorization (signature requirement) for Phase 2 Qualitative: It is logistically impracticable to collect signature for HIPAA authorization given we requested waiver of documentation of consent.

21.2.4. The research could not practicably be conducted without access to and use of the PHI:[86]

The use of PHI is necessary to meet the aims of the study.

22. Payments/Costs to Subjects[87]

22.1. Amount, method, and timing of payments to subjects:[88]

PWG Parent/caregiver/LAR/guardian members will each receive a $1,500 stipend during the PWG adaptation and implementation year, which requires weekly meetings during Month 1, monthly meetings for Months 2- 9, and an additional Process Evaluation discussion group (about 30 hours of meeting time). For the remaining project time, they will each receive a $500 annual stipend for participation, which will require approximately 8 hours of meeting time per year.

For the PWG Adaptation and Implementation year, we provide an estimated $50 per hour for our parent/caregiver/LAR/guardian members. For the years after that, the participation rate goes up to $62.50 per hour.

Parent/caregiver/LAR/guardian PWG members will be reimbursed by NCH-PCN study staff via ClinCard. After joining the PWG, parent/caregiver/LAR/guardian PWG members will be provided a ClinCard which will be loaded with stipend money at regular intervals over the course of the study. ClinCards will be collected at the end of the study and/or at the time of withdrawal for any parent/caregiver/LAR/guardian PWG members who withdraw.

PWG PARENT Coach and Provider and Clinic staff members, as well as the NCH-PCN Coach Coordinator will each receive $50 that will be loaded onto a NCH-issued ClinCard for their participation in the Process Evaluation interview or focus group. NCH-PCN study staff will provide ClinCards to them at the completion of their interview.

Phase 2 Qualitative interview participants will receive $100 on a ClinCard at the completion of their survey.

22.2. Reimbursement provided to subjects:[89]
PWG parent/caregiver/LAR/guardian members will receive reimbursement for travel and childcare expenses.

22.3. Additional costs that subjects may be responsible for because of participation in the research:[90]
None

23. Community-Based Settings[91]

23.1. Site(s) or location(s) in the community where the research team will conduct the research:
N/A

23.2. Composition and involvement of any community advisory board:
N/A

23.3. For research conducted outside of the organization and its affiliates:[92]

23.3.1. Site-specific regulations or customs affecting the research:
N/A

23.3.2. Local scientific and ethical review structure:
N/A

24. Resources Available

24.1. Qualifications (e.g., training, education, experience, oversight) of investigator(s) to conduct and supervise the research:[93]

Dr. Coker will be responsible for the overall design and management of the study. She will lead weekly SC-NCH research team meetings, provide critical guidance in the adaptation and implementation process, and direct the Coach training for all practices. Working closely with the NCH team, Dr. Coker will supervise data collection, and will work with the academic research team in all aspects of the study.

Dr. Coker is Department Chair and Professor of Pediatrics at University of Hawai'i, John A. Burns School of Medicine and Chief of Pediatrics at Hawai'i Pacific Health Medical Group. She is former Professor of Pediatrics at the University of Washington School of Medicine, Division Chief of General Pediatrics, and former Investigator at Seattle Children's Research Institute, Center for Child Health, Behavior, and Development. Dr. Coker is an internationally-recognized expert in the area of well-child care clinical practice redesign. She is a member of the United States Preventive Services Task Force (USPSTF), a member of the American Academy of Pediatrics Bright Futures, 4th Edition Expert Panel, and has received both national and international awards recognizing her work in well-child care clinical practice redesign. Dr. Coker has led two studies (as PI) to design and test new models of preventive care delivery for children in low-income families at community clinics and pediatric practices, funded by NIH and HRSA, and is currently leading a third that is a cluster RCT of the PARENT

intervention among a predominately low-income Latinx population at community clinics in Washington State and California.

Dr. Coker has expertise in approaches for community-engaged research, and in her previous and currently-funded research projects, she has utilized Project Working Groups to design and test well-child care delivery design interventions.

Dr. Lowry is a Senior Biostatistician with the Biostatistics, Epidemiology, and Analytics for Research (BEAR) Core at Seattle Children's Research Institute. She has collaborated with Dr. Coker as the study biostatistician on two NIH-funded R01 trials (PI: Coker), Text2Breathe, a multi-site trial of a parent text messaging intervention for asthma management, and currently, the cluster RCT of PARENT among low-income Latinx families in federally qualified health centers. In her capacity as Senior Biostatistician with the BEAR Core she contributes study design expertise, scientific oversight, and statistical analysis and planning, designing methodological approaches to suit the unique goals and challenges of various research projects. Her certification in Implementation Science research methods, and experience designing and conducting several program evaluations will add relevant expertise to the proposed project. These experiences further strengthen her ability to ensure that this research is both scientifically rigorous and generates results that are translatable and highly relevant to the needs and concerns of patients and other key stakeholders. Her statistical experience includes the application of linear, logistic, conditional and polytomous logistic regression, survival analysis, generalized linear models, generalized estimating equations, meta-analysis, use of propensity scores and multiple imputation, and power analysis.

Dr. Liljenquist is Assistant Professor of Pediatrics at the University of Washington School of Medicine, and Adjunct Assistant Professor at the University of Washington School of Public Health, and Investigator at Seattle Children's Research Institute, Center for Child Health, Behavior, and Development.

She obtained her PhD in Rehabilitation Sciences at Boston University, and a Masters of Public Health from the University of Washington. Her areas of expertise are in preventive care delivery to improve identification and intervention for vulnerable families and children at higher risk for developmental delay. She has worked closely with Dr. Coker on the ongoing PARENT trial, and conducted training for the Coaches for that study. Dr. Liljenquist has trained all three of the current coaches in the WA state and CA study of PARENT; these are two care coordinators and one Spanish language interpreter who had no experience in health education previously. In partnership with Dr. Coker, she manualized the PARENT Coach training, based on Bright Futures Guidelines; this PARENT Coach Training Manual will be an integral part of the training for the NCH coaches in this study.

Dr. Ellyson is the site Principal Investigator at Seattle Children's Research Institute and an Investigator with the Center for Child Health, Behavior, and Development at Seattle Children's Research Institute. She is a PhD-trained economist whose experience includes the application of quasi-experimental and causal inferences methods to evaluate the impact of health and other public policies on health outcomes. She provides methodological support and analysis for a variety of studies for the Center and has contributed to or has led studies on healthcare utilization and costs among post-surgical pediatric patients, family income and child achievement, brand competition impact on pharmaceutical prices, and systems and structures that that are aligned with preferences and goals of youth and young adults who experience violence and who use substances.

24.2. Other resources available to conduct the research:[94]

Nationwide Children's Hospital Primary Care Network (NCH-PCN) is one of the largest Children's Hospital owned primary care networks in the country. Its 12 practices serve a patient population that is over 96% publicly-insured, 50% Black, and 16% Latinx. For decades, it has provided high-quality, comprehensive primary care services to underserved families in

and around the urban and suburban areas of Columbus, Ohio. NCH-PCN has built an important partnership with Columbus' Black communities and is seen as a key source of culturally-responsive and equitable primary care. Because of the racial diversity of NCH-PCN health coaches and families, we can examine whether parent - coach racial concordance correlates with intervention impact.

NCH-PCN has a robust EHR (Epic), and a close partnership with Partners for Kids, the pediatric Medicaid Accountable Care Organization that covers over 90% of NCH-PCN patients. NCH-PCN and Partners for Kids have full capability in detailed data queries, and currently can complete data pulls on all of our primary outcomes and the majority of secondary outcomes.

25. Coordinating Center Procedures

25.1. Coordinating center institution:

Seattle Children's will be the coordinating center

25.2. If Seattle Children's is the coordinating center:

25.2.1. Process to ensure communication among sites:[95]

There will be a team kick off meeting, which will be focused on shared vision and mission and goals of the project and a review of previously agreed-upon operations, meeting schedules, timeline, milestones, and investigator roles for the project. This meeting will repeat annually during the project period to allow the team to revisit our vision, mission, goals, milestones, roles, and provide for dedicated time for Coach refresher trainings, continuing education, and team-building activities. We will also hold weekly research team operations meetings, monthly meetings for larger design and study conduct considerations, and on quarterly basis, the research team will meet to review overall team functioning, identifying any new threats or challenges to effective collaboration. Project coordinators will join all meetings as well.

NCH and SC are in different time zones, so our meetings will be scheduled during normal work hours for both time zones. The majority of meetings will be remote, and utilize audio and video conferencing, and our in-person meetings will occur as outlined in this application, whenever possible and in accordance with our institution policies on travel as it relates to COVID-19. When scheduled in-person meetings, such as the annual research team retreats cannot occur due to travel restrictions, these meetings will be moved to an interactive virtual meeting.

25.2.2. Process to ensure all site investigators conduct the study according to the IRB approved protocol and report all non-compliance:

Investigators will meet regularly to discuss study progress, review protocol changes, and review the process for reporting non-compliance. All investigators and study staff at external sites will be provided with the Seattle Children's investigator manual and relevant IRB SOPs.

25.2.3. Process to ensure all required approvals are obtained at each site:

We will work with NCH led by co-investigator Dr. Kemper, to ensure that all required approvals are obtained at all sites. Approved materials will be shared with partner sites via email and Microsoft TEAMs as soon as they are received by the central site.

25.2.4. Process to ensure all sites are informed of any problems and/or interim results:

Given that this is a minimal risk study we do not anticipate any problems or

results. Any potential problems or issues will be discussed at the regular meetings or communicated via email to team members across sites.

26. International Center for Harmonization of Good Clinical Practice (ICH-GCP)

26.1. If you have committed to conducting the described study per ICH-GCP, check this box: ☐[96]

- This is generally applicable for contracts with industry-sponsored studies or sponsor protocols. See your contract/agreement or Sponsor Documentation if you are unsure.
- Note that completing GCP training is a separate activity and does not automatically mean that you have committed to conducting the study per ICH-GCP.
  If you check the box, upload a current curriculum vitae (CV) for the PI to the "Other Attachments" section of the "Local Site Documents" SmartForm.

[1] Provide a list of the participating sites (pSITEs). pSITEs are those sites outside Seattle Children's that will rely on the Seattle Children's IRB as their IRB of record. All pSITEs should be listed even if no study procedures will occur at the site. Remove the heading if this is not a study where Seattle Children's IRB will serve as the IRB of record for other institutions.

[2] Include information if this protocol is associated with other IRB-approved studies (e.g. is this application the next part/phase of a previously approved application.

[3] In clinical trials, an endpoint is an event or outcome that can be measured objectively to determine whether the intervention being studied is beneficial. Some examples of endpoints are survival, improvements in quality of life, relief of symptoms, and disappearance of the tumor.

[4] Include information on a drug or biologic in this section if: (1) the study specifies the use of an approved drug or biologic; (2) the study uses an unapproved drug or biologic; (3) the study uses a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition; or (4) data regarding subjects will be submitted to or held for inspection by the Food and Drug Administration (FDA). Only include information on a device in this section if: (1) the study evaluates the safety or effectiveness of a device; (2) the study uses a humanitarian use device (HUD) for research purposes; or (3) data regarding subjects will be submitted to or held for inspection by the FDA. Please note that mobile medical applications may meet the definition of a device – see FDA Guidance.

[5] See the Investigator Manual HRP-103 for sponsor requirements for FDA-regulated research.

[6] Explain what IND exemption category applies to the drug and why. Note that a drug is not exempt from an IND unless all criteria for one category are met. See "HRP-306: Drugs" for more information.

[7] Explain what IDE exemption category applies to the device and why. Note that a device is not exempt from an IDE unless all criteria for one category are met. See "HRP-307: Devices" for more information.

[8] Explain why the device is NOT a significant risk device. A significant risk device means an investigational device that: (a) is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; (b) is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; (c) is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or (d) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

[9] Be sure to indicate if controls will be included and include information about why control arms are ethically acceptable.

[10] Describe all of the research procedures being performed. Be sure to make it clear which procedures apply to each subject population. When applicable, describe how research procedures differ from standard of care and/or affect standard of care. Describe any audio/video recording that will be involved.

[11] Attach all surveys, scripts, and data collection forms to the "Supporting Documents" page.

[12] Include information about the frequency of data collection.

[13] See HRP-001 - SOP – Definitions for definition of banking. Type N/A if not applicable. If the data is subject to NIH Genomic Data Sharing Policies or other data sharing policies (e.g. you will submit data to dbGaP, NDAR, FITBIR), indicate here. Note that sharing with federal policies requires information to be included the consent forms. See HRP-502 F Language Resource Text for sample language.

[14] If applicable, include a list of identifiers that will be banked.

[15] Be general (e.g., researchers' lab, clinic, etc.)

[16] Generally, data and/or biospecimens should be released in a coded, non – identifiable manner.

[17] Include a description of the process used to verify and document that any required approvals have been obtained prior to release of data/biospecimens from the bank.

[18] You can allow for use for broad purposes

[19] This includes putting results and/or data in the subject medical records.

[20] If your population will differ from the representative population where the study will take place (e.g., race, ethnic group, or gender), provide a rationale for the differences.

[21] Seattle Children's IRB prohibits the exclusion of populations based on language, socioeconomic status, physical characteristics (e.g., gender identity, age, ethnicity), sexual orientation, religion, or access to technology unless there is sufficient justification for the exclusion. Specifically for language, the cost of translation and/or interpreter services will not be considered sufficient justification for the exclusion of participants who use a language other than English in accordance with NIH guidelines, in most circumstances. ("Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources." 59 FR 11146, March 28, 1994). See Investigator Manual HRP-103 for additional information.

[22] The plan must take into consideration the purpose of the research and the setting in which the research will be conducted. The plan must ensure that no group of people is either unfairly over-represented or unfairly excluded from participating in research. Your response should include how the recruitment process and other aspects of the study (as appropriate) are designed to facilitate equitable selection.

[23] If you check a box below, be sure to include the additional considerations associated with the population.

[24] Refer to HRP-416 CHECKLIST: Children.

[25] If the study is minimal risk, explain why. For studies that present greater that minimal risk include, as applicable: (1) why direct benefits are anticipated, (2) why risks are justified by anticipated benefit and/or the relationship between risk and prospective benefit compared to available alternatives, (3) why risk represents only minor increase over minimal risk, (4) how study procedures are reasonably commensurate with those inherent to the child's actual or expected conditions, (5) whether the interventions/procedures are likely to yield generalizable knowledge about the participant's condition and why it is of "vital importance" to understanding or amelioration of the participant's underlying disorder or condition, and (6) an explanation of what alternative methods/approaches were considered to make the above assessments (as applicable). As applicable, provide evidence-based information to support your assessment.

[26] This population may be wards of the state or any other agency, institution, or entity. For studies that present greater than minimal risk, refer to HRP-416 CHECKLIST: Children, Section 6, for additional guidance on required considerations for this population.

[27] This refers to both cognitive impairments and adults who are incapacitated for any other reason. As applicable, refer to HRP-417 CHECKLIST: Cognitively Impaired Adults.

[28] This includes subjects and their parent(s)/LAR.

[29] Applicable to information conveyed in writing and verbally. For example, your plan could include translating all study documents and having a study team member or interpreter available who can speak the language to answer questions.

[30] Refer to HRP-413 CHECKLIST: Neonates and HRP-414 CHECKLIST: Neonates of Uncertain Viability.

[31] This box does not need to be checked if pregnant women are not a target population and pregnancy is irrelevant to risk considerations. Refer to HRP-412 CHECKLIST: Pregnant Women.

[32] Refer to HRP-415 CHECKLIST: Prisoners

[33] Indicate how you will ensure that there is no coercion or undue influence

[34] A subject is considered "enrolled" when they consent to be in the study.

[35] Only applicable for multisite studies.

[36] i.e., numbers of subjects excluding screen failures.

[37] Payment for participation is not considered a benefit.

[38] For example, data will be double entered, data will be reviewed by another study team member to ensure accuracy, etc.

[39] If your study is multisite and there are differences in how confidentiality will be maintained by the coordination center and our local site, this should be explained in this section (e.g. local site will have samples that are linked to a person's name, but the coordination center will only receive coded samples without any links). Confidentiality regarding use of Social Media will be explained in a protocol section below.

[40] Including the signed consent/assent/permission forms and any information/documentation collected during the consent process.

[41] Privacy refers to persons and their interests in controlling the access of others to themselves. For example, based on privacy interests, people want to control the time and place where they give information, the nature of the information they give and who receives and can use the information.

When providing a response, consider the subject population and nature of the study. For example, persons might not want to be seen entering a place that might stigmatize them, such as a pregnancy counseling center that is clearly identified as such by signs on the building.

[42] Applicable for studies that present more than minimal risk.

[43] Include information about who (describe in terms of role or group) will review the data.

[44] This should be specific to the social media you are using for the research.

[45] All communications that are directed towards subjects and specific to a particular study will require prior IRB review and approval. All non-IRB reviewable communications can be described in general terms by category – news stories, relevant publications – and representative examples of each can be provided.

[46] Applicable if the research involves more than minimal risk to subjects. If minimal risk, this section is N/A.

[47] If this is a multicenter study and subjects will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements) those methods should also be described here.

[48] If the study will enroll or seek permission from individuals who speak a language other than English and recruitment methods will differ for these individuals (e.g., they will be approached by a bi-lingual person outside the study team), be sure your description covers these methods as well.

[49] For example, subjects will be initially approached in a private room or a letter rather than a postcard will be sent when the study name may disclose health information about the potential subject.

[50] For example, medical records, CIS, clinical databases, other study records. If the study will access PHI for recruitment purposes without prior authorization from subjects, please address this in the HIPAA Authorization section below.

[51] Attach copies of these documents to the Recruitment Materials section of the study SmartForm. For printed advertisements, attach the final copy. For online advertisements, attach the final screen shots (including any images). When advertisements are taped for broadcast, send the final audio/video tape to IRB@seattlechildrens.org. You may attach the wording of the advertisement to the SmartForm prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.

[52] "Permission" refers to consent obtained from a parent or LAR.

[53]Address the following in the response, as applicable:

1. How you will ensure that subjects and/or their parent/LAR have sufficient opportunity to discuss and consider whether or not to participate in the research.
2. Speak to the suitability of the intended consent process for the intended audience, taking into consideration the subject's and/or parent/LAR's age, language, comprehension level, and familiarity with technology tools (if applicable).

3. If using an electronic process to send consent information or obtain documentation of consent (e.g., e-signature), identify the process to be used to send the consent information (e.g., e-mail).
4. If using an electronic process (e.g., e-mail), describe the procedures that ensure the electronic process allows subjects/parents/LARs to ask questions they may have before signing (e.g., by in-person discussions, telephone calls, videoconferencing). If conducting a consent conference, describe the method to be used for the conference (e.g., telephone call, video conference), specifying any programs (e.g., Zoom) to be used. If applicable, indicate that the consent discussion will be audio or video recorded and whether recording will occur within any programs being used (e.g., Zoom).
5. If using an electronic process, describe how the subject and/or parent/LAR will navigate the consent materials, including whether the subject/parent/LAR will have the ability to move backwards and forwards within the electronic system and to stop and continue at a later time. Also indicate how long it will take.
6. The availability of study personnel to assist subjects and/or their parent/LAR in using the electronic process, if applicable.

[54] Some study teams are currently considering creative solutions for such individuals; these potential solutions include snail mail, drive through paperwork for consent, and loaner device/hotspots for e-consenting. If no alternative will be made available (meaning these individuals cannot be enrolled), the IRB will look for a sufficient rationale for this exclusion.

[55] For example, the consent discussion will take place in a private room.

[56] Address the following in the response, as applicable:
1. Identify the means of documenting consent/assent/permission (e.g., in writing, verbally, etc.). If obtaining an electronic signature, identify the specific software/application to be used.
2. Include a description of how the consent/assent form(s) will be delivered, including any programs (e.g. REDCap) to be used.
3. Include a list of any information about the individual that will be collected during the assent/consent/permission process.
4. If the research is conducted outside of Washington State, provide confirmation that the electronic documentation of consent is legally effective in that jurisdiction. Note, the study team's location while conducting the study dictates the jurisdiction. For single IRB studies, the participating site's study team location while conducting the study dictates the jurisdiction.

[57] Electronic signature in this context refers to a legally effective electronic signature (e.g., a signature obtained via DocuSign) and does not apply to procedures where a waiver of documentation of consent is requested.
[58] Indicate "N/A" if not obtaining an electronic signature. Researchers are encouraged to consider the risks and benefits of the research when determining whether it is necessary to verify the subject/parent/LAR identity. For example, consider how likely it is that someone other than the subject would provide the consent. Social behavioral minimal risk research will not typically warrant identity verification.
[59] For example, consent forms will be downloaded as soon as they are full executed and saved electronically in a location accessible to the study team.

[60] This section describes the ways in which the procedures will not follow Seattle Children's SOP.

[61] See "HRP-411: Waiver or Written Documentation of Informed Consent" for further information.

[62] An information sheet template (HRP-502D) can be found in the Click IRB Library and should be attached to the consent form of the study SmartForm. For internet research, the information sheet can be translated to an on-line format, if desired.

[63] The IRB sometimes requires a script if you are having the consent conversation over the phone rather than in person. Templates for a consent script are available on the IRB website on the Participant Recruitment page and should be attached to the study SmartForm.

[64] This section describes the way(s) in which the processes for this study will not follow Seattle Children's SOP.

[65] Note the Short Form Consent may only be used when certain conditions are met. See HRP-091 for requirements for Short Form consent form use.

[66] For research conducted in the state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "children." The age of majority in Washington is 18; however, sometimes younger children have ability to consent for certain types of care (e.g. sexual reproduction/health; mental health; drug/alcohol treatment). For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "children" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." If the sites in other states in the study are conducting their own IRB review, you do not need to worry about this--type N/A. If you are conducting research and are actively recruiting participants outside of Washington who are NOT coming to SCH to give consent and who will be covered under SCH IRB approval, this section should be addressed in your protocol.

[67] For minimal risk studies and greater than minimal risk studies that offer a prospect of benefit, the IRB generally requires one parent to provide permission for the child to participate.

[68] If permission will not be obtained, please address this in the Waiver or Alteration of Consent Process below.

[69] See HRP-013 for more information.

[70] The IRB generally follows the following guidelines for written assent: children 7-12 should provide written assent on the "simple" assent form (HRP-502G); children 13-17 should provide written assent by co-signing the parental permission form (HRP-502A). The IRB will consider other assent scenarios (e.g. verbal assent for some or all children; not requiring assent for some or all children; or waiving assent): please provide details about the plan for your study. See HRP-090 and HRP-416 for more information on waiving assent and when assent is not necessary.

[71] See Appendix A-13 of the Investigator Manual HRP-103 for requirements for re-consent at age 18. If you think you meet the conditions for a waiver at 18, please address this in the Waiver or Alteration of Consent Process below.

[72] See "HRP-417 Cognitively Impaired Adults" for further information.

[73] For example: durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child. If you are following HRP-013 in order to make this determination, simply state that in this section. For research conducted in the state, review "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)" to be aware of which individuals in the state meet the definition of "legally authorized representative." For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of "legally authorized representative" in "SOP: Legally Authorized Representatives, Children, and Guardians (HRP-013)." If the sites in other states in the study are conducting their own IRB review, you do not need to worry about this--type N/A. If you are conducting research and are actively recruiting participants outside of Washington who are NOT coming to Washington to give consent and who will be covered under SCH IRB approval, this section should be addressed in your protocol.

[74] The IRB may allow the person obtaining assent to document assent on the consent document.

[75] Provide justifications/explanations for each subject population for which a waiver/alteration is being requested.

[76] For example: consent/parental permission will not be obtained, required information will not be disclosed, the research involves deception, waiver for participants who turn 18, waiver for information collected about a non-present parent, or other waivers as necessary.

[77] The IRB needs to make all the waiver findings and key to this determination is that the IRB understand why it is not practicable to do the research without a waiver of consent. You need to provide a rationale in order for the IRB to consider whether the waiver criteria are met. See "HRP-410: Waiver or Alteration of the Consent Process" for further information.

[78] Possible reasons might include: a) you are not collecting information that could put subjects or their families at harm, e.g., affect eligibility for insurance, employability, stigmatization; b) you are not collecting information that would

alter or affect the subject's care; c) any publication or presentation of research results would be done in a manner that would never reveal an individual's identity either directly or indirectly.

[79] Possible reasons could be: a) inability to locate families because of the lengthy time period over which the records/samples were created; b) many of the subjects whose records, data, or biospecimens will be used may have died and contacting the families about the research could cause harm and anguish to families; c) all eligible patients must be included in the study for the results to be meaningful.

[80] For example, identifiers are necessary, so that researchers can perform quality checks or identifiers are necessary to link data from multiple sources.

[81] See "HRP 419: Waiver of Consent for Emergency Research" for further information.

[82] PHI is health information that is also identifiable because it includes one or more of the 18 HIPAA identifiers. See Investigator Manual HRP-103 for the list of HIPAA identifiers.

[83] If your study involves using or creating PHI and your only contact with participants is online, you can request an alteration of HIPAA authorization to remove the signature requirement. As an alternative to a waiver of documentation of consent and an alteration of HIPAA authorization, you must demonstrate that the electronic consent signatures are compliant with applicable state/international law (in Washington, see RCW 19.34.300).

[84] For example: altering HIPAA elements for international research.

[85] Provide justifications/explanations for each subject population for which a waiver/alteration is being requested.

[86] Possible reason could be: the nature of the research is specific to individuals' health and requires access to individuals' health records.

[87] See "HRP-316: Payments" for further information.

[88] Methods of payment include check, ClinCard, gift cards, etc. Provide details on who will be the recipient of the payment (parent or child).

[89] Reimbursement is used when the subject is paid back for travel expenses such as transportation, food, childcare, or lodging. Reimbursement is generally distributed to person who incurred cost (usually parent) and requires receipts to be submitted.

[90] This could include things like fuel/transportation costs, parking, and/or childcare.

[91] Community-based settings may include community clinics, schools, non-profit organizations, etc.

[92] Type N/A if this section does not apply.

[93] Provide enough information to convince the IRB that the principal and/or co-investigator(s) are appropriately qualified to conduct and supervise the proposed research. When applicable, describe their prior clinical experience with the test article or study-related procedures, or describe their knowledge of the local study sites, culture, and society.

[94] For example, as appropriate: (1) Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit? (2) Describe the time that you will devote to conducting and completing the research. (3) Describe the facilities in which the research will be conducted. (4) Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research. (5) Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.

[95] Including communication between sites of current study document versions and modifications.

[96] If you check the box, you are required to conduct your study according to the principles outlined at https://www.ich.org/products/guidelines/efficacy/efficacy-single/article/integrated-addendum-good-clinical-practice.html.