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FAMILIES, CHILDREN and TEACHERS THRIVING TOGETHER

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Statement of Compliance

This study will be conducted in accordance with the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), any other applicable US government research regulations, and institutional research policies and procedures. The Principal Investigators will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the study participants. All personnel involved in the conduct of this study have completed Human Subjects Protection Training.

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List of Abbreviations

AE	Adverse Event/Adverse Experience
CEHD	Center for Early Childhood Health and Development
CFIR	Consolidated Framework for Implementation Research
CFR	Code of Federal Regulations
CRF	Case Report Form
CSOC	Clinical Study Oversight Committee
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DOE	Department of Education
FE	Family Engagement
FFR	Federal Financial Report
FWA	Federal wide Assurance
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
IRB	Institutional Review Board
N	Number (typically refers to participants)
NIH	National Institutes of Health
NYC	New York City
NYU	New York University
OHRP	Office for Human Research Protections
OHSR	Office of Human Subjects Research
PC	ParentCorps
PI	Principal Investigator
PKFA	Pre-K for All
Pre-K	Pre-Kindergarten
PL	Professional Learning
RCT	Randomized Controlled Trial
SEC	Social Emotional Competencies
SEL	Social Emotional Learning
SEF	Social Emotional Functioning
SiR2T	Self in Relation to Teaching
US	United States

Protocol Summary

Title	Families, Children and Teachers Thriving Together
Short Title	Families, Children and Teachers Thriving Together
Brief Summary	<p>The current study examines the impact of <i>ParentCorps</i> in high-poverty district schools in New York City (NYC). The study is conducted within the context of the NYC Department of Education (DOE) Pre-K Thrive initiative. As part of this initiative, the Center for Early Childhood Health and Development (CEHD) at NYU Langone Health is implementing services to strengthen family engagement and support parents and teachers in creating safe, nurturing and predictable environments for young children. Services include resources to support social emotional learning (SEL) and family engagement (FE) for all Pre-K for All (PKFA) programs and all PKFA families; <i>Thrive Professional Learning</i> to support the use of evidence-based SEL and FE practices for teachers and leaders from 350 PKFA programs; and <i>ParentCorps</i> programs for PKFA children and families in 50 PKFA programs (which is a subset of PKFA programs receiving Professional Learning).</p> <p>The current study evaluates the relative value of <i>Thrive Professional Learning plus ParentCorps</i> compared to <i>Thrive Professional Learning</i> compared to standard supports for pre-K programs (which includes <i>Inspire Professional Learning</i>).</p> <p>The sample includes 3,370 Pre-K students and their parents across 81 district schools (20 receiving <i>Thrive Professional Learning plus ParentCorps</i>, 21 receiving <i>Thrive Professional Learning only</i>, and 40 receiving <i>Inspire Professional Learning</i>). All 3,370 families will be invited to participate; 1,700 are expected to consent, with a ~50% consent rate). All parents of Pre-K students in the 81 district schools will be invited for them and their Pre-K children to participate in the study, which includes 1 school-based assessment in Pre-K in Spring and 1 school-based assessment at the end of Kindergarten, and teacher ratings of children twice in Pre-K and once in Kindergarten. Additionally, parents will be invited to consent to the use of their children's NYC DOE administrative records from Pre-K through grade 5 for the purposes of this study. Parents will also be invited to participate by completing surveys with NYU study staff. Parents will be consented to complete five surveys over their child's first three school years: two surveys in Pre-K (Times 1 and 2), two surveys in Kindergarten (Times 3 and 4) and one survey in Grade 1 (Time 5).</p>

Objectives	<p>Impact on Students: The primary aims of this study are to examine the impact of <i>ParentCorps</i> on children's social emotional learning and academic skills. Secondary aims explore: 1) <i>ParentCorps</i> impact on child well-being; 2) pathways through which <i>ParentCorps</i> impact on child social-emotional learning may mediate impacts on academic skills; 3) pathways through which <i>ParentCorps</i> impact on parents' well-being may mediate impacts on parenting and ultimately child social-emotional learning and academic skills; and 4) the moderating role of context (family, classroom, school, neighborhood and covid-19) and baseline characteristics on <i>ParentCorps</i> impact and child outcomes.</p> <p>Impact on Families: The primary aims of this study are to examine the impact of <i>ParentCorps</i> on parenting practices and family engagement. Secondary aims examine the impact of <i>ParentCorps</i> on parents' well-being (depression, stress, social support and parent self-efficacy).</p>
Methodology	<p>Randomized controlled trial.</p> <p>This study is a hybrid implementation-effectiveness design.</p>
Endpoint	<p>Impact on Students: The study primary outcomes are students' social-emotional learning and academic skills.</p> <p>Impact on Families: The study primary outcomes are parenting practices and family engagement.</p> <p>Secondary outcomes are child well-being and parent well-being.</p>
Study Duration	<p>Study with Students: September 1, 2019 – June 30, 2021 (teacher report on students); March 1, 2020– June 30, 2021 (direct student participation); September 1, 2019 – June 30, 2026 (student administrative records)</p> <p>Study with Parents: September 1, 2019 – June 30, 2022</p>
Participant Duration	<p>Parents of pre-K students will be invited to participate in the study in Fall 2019. They will be invited to provide consent for participation for both their pre-K child and themselves. Students will participate in school-based assessments in Spring 2020, when they are in pre-K, and in Spring 2021, when they are in Kindergarten. Students will be rated by their Pre-K teachers at two time points (Fall 2019 and Spring 2020) and by their Kindergarten teachers at one time point (Spring 2021). Parents will complete 5 surveys with study staff in Fall 2019 and Summer 2020, when their children are in pre-K, Fall 2020 and Spring/Summer 2021 when their children are in Kindergarten and Spring/Summer 2022 when their children are in Grade 1.</p>
Population	<p>All pre-K students, and their parents, from these 81 district schools in New York City will be invited to participate in the study. The only eligibility criterion is that parents/caregivers speak English or Spanish (~90% in study schools).</p>

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Study Sites	81 district schools (20 receiving <i>Thrive Professional Learning plus ParentCorps</i> , 21 receiving <i>Thrive Professional Learning only</i> , and 40 receiving <i>Inspire Professional Learning</i>).
Number of participants	A maximum of 3,370 pre-K parents and students will be invited to participate in the study. 1,700 families (~50% consent rate) are expected to participate in the study.
Statistical Analysis	Hierarchical Linear Modeling (HLM) or other mixed effects models will be employed to estimate the impact of <i>Thrive Professional Learning plus ParentCorps</i> versus <i>Thrive Professional Learning only</i> versus <i>Inspire Professional Learning</i> on parent and student outcomes.

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2. Introduction, Background Information and Scientific Rationale

2.1 Background Information and Relevant Literature

Socioeconomic Adversity, Child Development and Parenting

A robust literature documents the impact of socioeconomic adversity on child development, implicating poverty as a key factor underlying racial/ethnic disparities in learning, behavior, and health (e.g., Blair & Raver, 2012). Children living in low-income urban neighborhoods are exposed to stressors related to poverty and discrimination. In the US, 80% of the population lives in urban areas, and racial/ethnic minority children are 6 to 9 times more likely than White children to live in concentrated poverty. Despite major policy initiatives, these children remain at high risk for underachievement and school dropout (Stetser & Stillwell, 2014). At least half of the well-documented achievement gap for low-income, minority children is already present in kindergarten (Burchinal et al., 2011).

The learning that occurs (or does not occur) in the first years of schooling may be the most critical in shaping lifelong academic trajectories (Belsky & MacKinnon, 1994; Entwisle & Alexander, 1989; Jimerson, Egeland, Sroufe, & Carlson, 2000). Disparities in school readiness are attributable, in part, to limited opportunities for acquiring foundational skills (e.g., social-emotional, behavior regulation) necessary for school success. Stressors of poverty interfere with brain development and the acquisition of foundational skills. Additionally, low-income children are less likely to have access to high-quality education (Nores & Barnett, 2014). Strengthening school readiness is a critical strategy for closing the achievement gap and promoting lifelong success, well-being and productivity. This is particularly true for students who enter school without adequate self-regulation skills (~20% in urban schools). Social-emotional and behavior regulation skills promote on-task behavior and executive functioning and reduce disruptive interactions with teachers and peers (Izard et al., 2001; Rhoades et al., 2011). Students without these skills are more likely to develop behavior problems that interfere with learning (Arnold et al., 1999; McEvoy & Welker, 2000), in part because schools are not equipped to respond proactively when students are dysregulated and often resort to exclusionary discipline practices.

Several key early childhood studies demonstrate the potential for high-quality home and classroom environments to promote self-regulation, a core component of school readiness and foundational for achievement (Heckman, 2011; McClelland, Morrison, & Holmes, 2000; Moffitt et al., 2011; Olds et al., 2004; Pianta, Mashburn, Downer, Hamre, & Justice, 2008; Raver et al., 2011; Raver & Zigler, 1997; Rhoades, Warren, Domitrovich, & Greenberg, 2011). Substantial evidence indicates that the nature and quality of interactions between teachers and students predict both learning and behavioral outcomes (Pianta, Barnett, Burchinal, & Thornburg, 2009). Regarding the home environment, the nature and quality of parent-child interactions are related to brain development, self-regulation and learning (Areepattamannil, 2010; Belsky & de Haan, 2011; Blair & Raver, 2012; Joussemet, Koestner, Lekes, & Landry, 2005; Kiser & Black, 2005; Shonkoff et al., 2012; Shonkoff & Phillips, 2000). Specific aspects of parenting are strongly linked to child development, including support for positive behavior, behavior management, and involvement in education (e.g., Hill & Craft, 2003; Patterson & Stouthamer-Loeber, 1984). The stressors

associated with poverty and social disadvantage can make it difficult for parents to engage in nurturing relationships and effective behavior management (Evans & Schamberg, 2009; McLoyd, 1990). Poverty constrains parenting resources and jeopardizes successful development of self-regulation (Blair & Raver, 2012). Transactional social learning models predict that behavioral dysregulation and disrupted parenting set in motion a cascade toward conduct problems and school failure (e.g., Shaw et al., 2000). “Early-starter” models of conduct problems implicate behavioral dysregulation (i.e., noncompliance) in precipitating coercive parent-child interactions, characterized by hard and inconsistent behavior management and inadvertent reinforcement of misbehavior (Shaw et al., 2000).

Parenting is determined by a confluence of factors, including parents’ social and psychological resources, child characteristics, socialization goals, and cultural norms and values (Belsky, 1984; Bornstein, 2016; Bronfenbrenner, 1979; Garcia-Coll et al., 1996; Harkness et al., 1992). Economic hardship, financial strain, and social stressors (e.g. fear for safety, discrimination) affect young children indirectly via their negative impact on parent mental health and well-being (Barajas-Gonzalez & Brooks-Gunn, 2014; Mistry, Vandewater, Huston, & McLoyd, 2002), which ultimately challenge parents’ capacity to respond in children in warm, responsive ways (Conger et al., 1994; McLoyd, 1990, 1998; Mistry, Vandewater, Huston, & McLoyd, 2002). Further, decades of research findings attest that individuals living in poverty are more likely than their counterparts to experience psychological distress (Belle, 1990; Brown, Bhrolchain, & Harris, 1975; Lorant, Eaton, Philippot, & Ansseau, 2003). Among women, those who live in financially strained circumstances and who have responsibility for young children are more likely than other women to experience symptoms of depression (Belle, Longfellow & Makowsky, 1982). A robust literature identifies social support as a protective factor that promotes health and well-being among individuals across the life-span. For parents, social support shapes expectations, imparts knowledge and diminishes stress related to parenting to ultimately promote reliance on positive and effective parenting practices while decreasing reliance on punitive parenting practices (see Serrano-Villar, Huang & Calzada, 2017).

Contextual factors play an important role in children’s development, parent-child relationships and parenting. The COVID-19 pandemic has added additional stressors to families. In the United States, school closures related to the coronavirus pandemic have impacted hundreds of thousands of U.S. public and private schools and teachers, and millions of students. By March 24, 2020, 46 states made the decision to close schools, impacting more than 54 million students nationwide (out of 56 million students). For families, this resulted in disrupted routines, immediate shift to online learning and additional challenges balancing work-family responsibilities. Additionally, many parents and children experienced personal anxiety and worry related to the pandemic, and additional stressors at home, including technological challenges, taking care of family members, childcare or helping their own children with distance learning. Families have also been faced with financial stressors, loss of jobs and food insecurity. COVID-19 has also disproportionately impacted communities of color. These factors can significantly impact children’s and adult’s well-being and parent-child interactions, and can have long term impact of mental health, physical health, sleep and academic performance.

1.1 Rationale

Pre-K, ParentCorps and Thrive Professional Learning

Studies of early child development underscore the importance of intervening early to mitigate stress and support children's learning at home and school, particularly for children living in poverty (e.g., Shonkoff et al., 2011). Improving developmental trajectories among high-risk children early in life has been shown to yield a broad range of long-term benefits (Olds et al., 1998). Numerous trials show that universal intervention (for all children in at-risk populations) can improve outcomes for all, with the greatest benefits for those at highest risk (e.g., Reid, Webster-Stratton, & Baydar, 2004). However, poverty is typically associated with smaller intervention impact (Lundahl, Risser & Lovejoy, 2006), and the vast majority of families raising young children in low income, urban neighborhoods do not have access to evidence-based interventions. To reduce racial/ethnic and socioeconomic disparities in the USA, interventions must be broadly available, engaging, and effective for low-income, minority families living in large urban centers.

There is great demand for evidence-based interventions to enhance Pre-K, especially interventions for culturally-diverse, low-income populations. *ParentCorps* is a family-centered intervention that promotes foundational skills in pre-kindergarten, strengthens family engagement and helps parents and teachers provide high-quality environments. Two cluster (school) randomized controlled trials (RCTs) in high-poverty schools document the impact of *ParentCorps* on social emotional learning and academic outcomes (Brotman et al., 2011, 2013, 2016; Dawson-McClure et al., 2015). Both trials were conducted in authentic education settings (18 NYC public schools with Pre-K programs) and the intervention was provided universally (for all Pre-K students).

ParentCorps includes three key components: 1) *Professional Development, Program Training and Coaching*; 2) *Program for Parents of Pre-K Students*; and 3) *Program for Pre-K Students*. The three intervention components are expected to strengthen relationships and communication between parents and teachers and promote safe, nurturing and predictable environments, which contribute to child mental health and achievement.

Thrive Professional Learning is based on *ParentCorps Professional Development* and covers best practices in Family Engagement and Social Emotional Learning and includes an experiential approach to behavior change that asks learners to take the perspective of others and consider their own beliefs and assumptions about students, families, teachers and leaders.

Inspire Professional Learning is led by the NYC Department of Education. Professional Learning sessions are tailored to the needs of pre-K teachers and leaders, and include topics aligned with the district's quality standards that support child instructional goals.

The primary aim of this study examines the relative impact of Thrive Professional Learning plus *ParentCorps* relative to Professional Learning alone and Inspire Professional Learning on Pre-K teachers and classrooms.

2.2 Rationale

The current study examines the implementation and impact of *ParentCorps* in high-poverty district schools in 81 district schools in New York City. In NYC, the Mayor and Department of Education (DOE) have committed to expanding Pre-K to be truly universal. As part of this initiative, the NYC DOE provides Professional Learning to all 1850 Pre-K sites (schools and centers), across four tracks (Thrive, Create, Inspire, Explore). The Center for Early Childhood Health and Development (CEHD) at NYU Langone Health is implementing services to strengthen family engagement and support parents and teachers in creating safe, nurturing and predictable environments for young children. Services include resources to support social emotional learning (SEL) and family engagement (FE) for all Pre-K for All (PKFA) programs and all PKFA families; Thrive Professional Learning to support the use of evidence-based SEL and FE practices for teachers and leaders from 350 PKFA programs; and *ParentCorps* programs for PKFA children and families in 50 PKFA programs (a subset of PKFA programs receiving Thrive Professional Learning). The study is conducted within the context of the NYC DOE Pre-K Thrive initiative.

This hybrid implementation-effectiveness study evaluates the impact of Thrive Professional Learning plus *ParentCorps* compared to the Thrive and Inspire Professional Learning tracks alone on students and families. Eighty-one (81) district schools with Pre-K programs in high poverty NYC neighborhoods were selected for the study in late Spring 2017 by the NYC Department of Education (NYC DOE), following a detailed methodology developed collaboratively by the NYC DOE and NYU Investigators. Twenty (20) schools were randomized to Thrive Professional Learning plus *ParentCorps*, 21 schools to Thrive Professional Learning only and 40 schools to Inspire Professional Learning.

Note that there is a companion study “Teachers Thriving Together” (s19-00204) that includes Pre-K teachers from the same 81 study schools. The study investigates the impact of Thrive Professional Learning versus Inspire Professional Learning, and the impact of Thrive Professional Learning plus *ParentCorps* on teachers and classrooms.

2.3 Potential Risks & Benefits

2.3.1 Known Potential Risks

There is minimal risk involved in participating in this study for families and students. The parent survey focuses on parenting, parent well-being and children’s feelings and behaviors at home. The assessment with Pre-K students measures children’s social-emotional learning and academic skills. Children will be asked to complete tasks that measure learning about language and feelings, and their attention and memory skills. Children’s height and weight will also be collected. Teachers report on children’s feelings, behaviors and learning at school. There is no collection of Personal Identifiable Information (PII) as part of the child study record.

Despite the minimal risk in participating in the study, it is possible that parents or students will experience some inconvenience, embarrassment, or discomfort while completing the assessments or participating in surveys with NYU study staff. To minimize these risks, all

study staff will be trained by Co-I Barajas-Gonzalez in conducting surveys with parents in both English and Spanish; Dr. Barajas-Gonzalez has extensive experience in conducting interviews with parents in school-based settings in prior trials with a similar interview battery. Additionally, all study staff who will conduct assessments will have prior experience conducting assessments with young students. Co-Is Ursache and Kamboukos will oversee the training of assessors. Co-PI Dawson-McClure and Co-Is Kamboukos and Ursache also have extensive experience in conducting school-based assessments in school settings, and will inform procedures for these assessments and training of staff. Parents and students will also be informed that responding to the questions in the survey and school-based assessment is voluntary and that they may choose not to answer certain questions, end the survey or assessment early, and/or discontinue their participation in the study entirely.

Another potential risk to participants is a loss of confidentiality. All necessary steps will be taken to ensure the confidentiality of data. All study data will not be identifiable, therefore protecting the parents and students. Data will only be “identified” by a unique study number and will be entered securely into RedCap. Assessment and survey data captured and entered electronically will be set up so that the capturing and recording of PII (including names and IP addresses) are deactivated. All files finalized for analyses will be de-identified and saved in a secure, password protected network drive. All identifiable information (name, date of birth) captured or entered electronically, from the consent forms or during the survey with parents, and master file linking each parent and student to the study identification number, will be captured and stored securely, in RedCap, with limited and restricted access to study staff. Any information collected on paper (e.g., contact information, consent forms) will be stored in locked cabinets in secured office space, with restricted access to the NYU study team.

Only select NYU study staff will have access to data with identifying information. All data will be presented in aggregated form. Reports, grant applications and publications will be written in such a manner that individuals will not be able to be identified. Parents and students in participating schools are free to refuse to participate in the research activities without negative consequences to the students’ academic standing or opportunities within the Centers or the NYC Department of Education.

2.3.2 Known Potential Benefits

There are no direct benefits to families or students. The results of this study will be used to improve *ParentCorps* and will potentially have important implications for education policy and practice. Results can add to our understanding of the potential impact of school-based prevention programs on students. The results of the study may inform next steps for broad scale adoption and implementation of services within PKFA within the NYC DOE to build more nurturing and predictable classroom and home environments and increase family engagement to support children’s social emotional learning that is foundational to academic achievement and mental health.

3. Objectives and Purpose

3.1 Primary Objective

The overall objective of the study is to examine the impact of Thrive Professional Learning plus *ParentCorps* compared to the Thrive and Inspire Professional Learning tracks on child and family outcomes.

Specific Aim 1: To evaluate the impact of *ParentCorps* on: 1) children's social-emotional learning (social/interpersonal skills, executive function) and academic skills and 2) parenting practices and family engagement.

We hypothesize that families and children in sites with Thrive Professional Learning plus *ParentCorps* will have higher social-emotional learning and academic skills, and effective parenting practices than those in sites with Thrive and Inspire Professional Learning alone.

3.2 Secondary Objectives

Specific Aim 2: To evaluate: 1) *ParentCorps* impact on child well-being (feelings and behavior) and parent well-being (depression, stress, social support, parent self-efficacy); 2) pathways through which *ParentCorps* impact on child social-emotional learning may mediate impacts on academic skills; 3) pathways through which *ParentCorps* impact on parents' well-being may mediate impacts on parenting and ultimately child social-emotional learning and academic skills; and 4) the moderating role of context (family, classroom, school, neighborhood, and stressors related to COVID-19 and school closure) and baseline characteristics on *ParentCorps* impact and child outcomes.

Families and children in sites with Thrive Professional Learning plus *ParentCorps* will have better parent and child well-being than those in sites with Thrive and Inspire Professional Learning alone.

Specific Aim 3: To predict parent and child outcomes from contextual factors at multiple levels (child, family, classroom, school, neighborhood). Consideration of contextual factors as a predictor of parent and child outcomes will include COVID-19 stressors, and make use of the timing of assessments before, during, and after school closure.

Exploratory aims focus on the impact of *ParentCorps* on child health (body mass index, sleep).

Figures 1-2 depict the Theory of Change for the primary aim and outcomes.

Figure 1: Theory of Change for Primary Aim (Students)

The visual below depicts the Theory of Change for the primary aim on the impact on students from Thrive Professional Learning and *ParentCorps* (see Figure 1).

PARENCORPS THEORY OF CHANGE

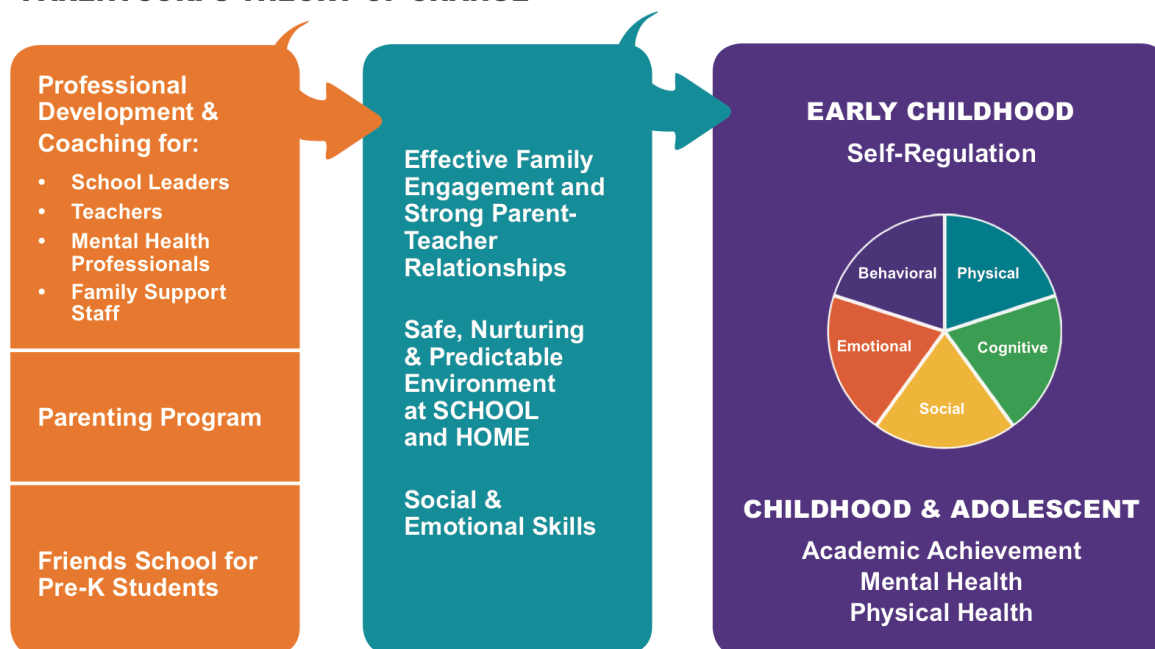
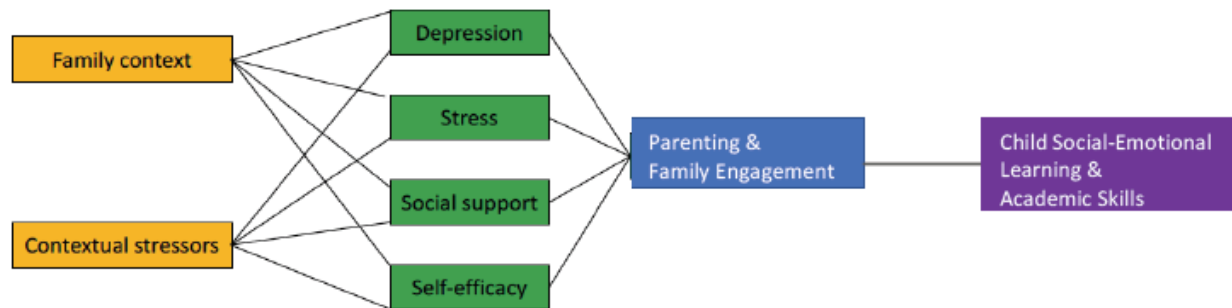


Figure 2. Theory of Change for Primary Aim (Parents/Families)

The visual below depicts the Theory of Change for the primary aim on the impact on parents, and ultimately, students (see Figure 2).



4. Study Design and Endpoints

4.1 Description of Study Design

This randomized controlled trial is an evaluation of Thrive Professional Learning plus *ParentCorps* compared to the Thrive and Inspire Professional Learning tracks in 81 district schools. The study will include families of Pre-K students and Pre-K students. Forty-one (41) district schools are participating in Thrive Professional Learning, delivered by NYU Langone-based staff; 20 of these schools are randomly assigned to implement *ParentCorps* (in addition to Thrive Professional Learning). Forty (40 district schools) are participating in Inspire Professional Learning and will not implement ParentCorps.

Study primary outcomes include child social-emotional learning and academic skills, and parenting practices and family engagement. The secondary outcomes are child well-being and parent well-being. Exploratory outcomes include child physical health (body mass index and sleep).

See Figure 3 for the schematic of the Study Design.

Figure 3: Schematic of Study Design

Prior to
Enrollment
Fall 2019

3370 Families/Students: Invited to participate in study (Fall 2019)

1700 families expected to consent



Fall 2019
Visit 1

Pre-K teacher report on students

Parent Survey



**Spring/
Summer
2020**
Visit 2

School-based assessment with Pre-K students & teacher report on students

Parent Survey

NYC DOE Administrative Data



Fall 2020
Visit 3

Parent Survey



**Spring/
Summer
2021**
Visit 4

School-based assessment with students (Kindergarten) & teacher report on students attending the 81 schools in Kindergarten

Parent Survey

NYC DOE Administrative Data



**Spring/
Summer 2022**
Visit 5

Parent Survey

NYC DOE Administrative Data

5. Intervention

5.1 Study Intervention Description

ParentCorps includes three key components: 1) *Professional Development, Program Training and Coaching*; 2) *Program for Parents of Pre-K Students*; and 3) *Program for Pre-K Students*. The three intervention components are expected to strengthen relationships and communication between parents and teachers and promote safe, nurturing and predictable environments. These changes scaffold children's acquisition of self-regulation skills, and together, sustained changes in the environment and self-regulation capacity contribute to mental health and achievement in childhood and ultimately, adolescence. *ParentCorps* implementation processes and materials were developed based on extensive implementation experiences, adult learning principles, and research on professional learning strategies that support sustained behavior change.

Professional Development is provided to support leaders, teachers, mental health professionals and parent support staff to advance knowledge, beliefs, skills and practice and *Training and Coaching* prepare school staff to implement and sustain *ParentCorps Programs* with fidelity. The *Program for Parents (Parenting Program)* is implemented by a mental health professional and offered to groups of ~15 parents during the school day and during after school hours. The Program for Parents includes 14 2-hour sessions provided weekly over a 4-month period. The *Program for Students (Friends School Social Emotional Learning Program)* is implemented by classroom teachers in the classroom with 90-minute lessons and activities once a week for 14 weeks.

Thrive Professional Learning is based on *ParentCorps Professional Learning* and was designed at the request of the NYC Department of Education to align with their Professional Learning Track system for Pre-K for All teachers and leaders. Thrive Professional Learning is delivered to teachers in groups of 20–40 4 times a year over a two-year period. Thrive Professional Learning is delivered to leaders in groups of 20 – 40 three times a year over the same two-year period. Content covers best practices in Family Engagement and Social Emotional Learning and includes an experiential approach to behavior change that asks learners to take the perspective of others and consider their own beliefs and assumptions about students, families, teachers and leaders.

Inspire Professional Learning is led by the NYC Department of Education. Professional Learning sessions are tailored to the needs of pre-K teachers and leaders, and include topics aligned with the district's quality standards that support child instructional goals.

5.2 Administration of Intervention

ParentCorps is a family-centered intervention that is delivered in Pre-K settings (district schools and Early Childhood Education Centers). All Pre-K students and families of sites that implement *ParentCorps* are invited to participate in the program. Embedding a parenting intervention in schools is key for reach and accessibility. Although we do not assume that all parents should prioritize participating in preventive interventions, in order to reduce racial, ethnic, and socioeconomic disparities, interventions must be accessible,

engaging and effective. As with many evidence-based parenting programs, *ParentCorps* aims to minimize logistical barriers experienced by many families in low-income communities by providing meals, childcare, and a venue in close proximity to home. Outreach messaging expresses value for parents, frames the goal of the intervention as “helping children succeed” and explicitly links children’s experiences at home with school success (bolstering parents’ perceived benefits and influence; Ajzen, 1991). Every Pre-K family is invited and parents are always welcome to join regardless of the parameters (e.g., arriving late from work, unable to attend every session). Core outreach strategies include *ParentCorps* brochures and sign-up sheets sent home, posters hung visibly in the school, endorsement of the program by leaders, and individual communication by phone or in person in the course of daily interaction at school. Activities have been built into sessions to support frequent attendance and scaffold practicing of new strategies (including reinforcement of attending, arriving on time, and practicing strategies via tickets that are entered into drawings for metro cards). Each session ends with planning for home practice and begins with problem-solving any barriers encountered. Parents receive a photograph-based guide for Parents from Parents, which includes take-aways for each strategy and tool and “Bring it Home” pages with step-by-step instructions to try the strategy at home and simple charts to monitor how it went. Tools to help put strategies into practice include routine chart, praise magnet, and CD of songs for active play and calm down (Dawson-McClure et al., 2017).

Early childhood staff (Pre-K teachers and mental health professionals) are trained and coached to implement the program. The Program for Students and Parents are 14-week sessions, delivered weekly, over a 4-month period.

Thrive Professional Learning is offered as part of the Professional Learning Track system for all Pre-K for All teachers and leaders. The NYC DOE schedules Thrive Professional Learning training days for staff on non-attendance days. Teachers attend four Professional Learning days annually, and leaders attend three days annually, over a two-year period.

5.2.1 Procedures for Training and Monitoring Intervention Fidelity

Teachers and mental health professionals who implement *ParentCorps* receive Professional Development prior to launching the Program. *Professional Development* is provided to support teachers to advance knowledge, beliefs, skills and practice and *Training and Coaching* prepare school staff to implement and sustain *ParentCorps Programs* with fidelity. Teachers in *ParentCorps* receive Training and Intensive Coaching on the Social Emotional Learning Program and manuals and all the resources necessary to implement the program with fidelity.

ParentCorps Professional Development is intended to promote knowledge, beliefs, skills and practices necessary for sustained behavior change through intentionally sequenced group and individualized experiences, with a “spirit” of explicitly valuing collaboration and supporting autonomy. It includes four elements:

1) *ParentCorps FUNdamentals* is a series of large-group experiential PD days (in groups of 25-40 participants from across all schools) which takes place in the first summer prior to

implementation. Leaders participate in a 2-day *FUNDamentals* series with leaders from other schools. The *FUNDamentals* series is aimed at creating a shared understanding of influences on school readiness and the rationale and evidence for *ParentCorps* components, and motivating participants to use evidence-based practices to engage families and create nurturing and predictable classrooms (e.g., creating responsive interactions, scaffolding and reinforcing new skills, and consistent routines, rules and consequences). In a safe and supportive setting, facilitators are asked to reflect on their assumptions (positive and negative) about parents and students and to connect those assumptions to their current practices and ability to help children learn and succeed.

2) *ParentCorps 101 E-learning* is a self-paced interactive web-based series with 7 modules intended to help facilitators build confidence and mastery of evidence-based practices.

3) *Training* is a group-based series to prepare facilitators (mental health professionals and teachers) to implement *Programs* with fidelity and to ensure high levels of exposure by parents and students. Mental health professionals are supported to facilitate the Program for Parents (day and after-school versions) with fidelity. Pre-K teachers and assistants are supported to implement the Program for Students in the classroom. In addition, early childhood staff (including Kindergarten teachers as needed) is trained to facilitate the *Program for Students* during after-school hours in parallel with the *Parenting Program*. All facilitators receive training on engaging parents to participate

4) *Coaching* is one-on-one support provided in-vivo and from a distance (phone, text, email) to help users apply evidence-based practices in daily interactions with students and parents, and to support high levels of implementation fidelity and exposure. All Pre-K teachers and mental health professionals facilitating ParentCorps receive four on-site coaching visits and 10 30-minute calls for the remaining sessions in the first year for each cycle of implementation.

Fidelity, quality of implementation and exposure are captured and monitored throughout coaching. These are captured through self-report measures by facilitators, which are entered and monitored in real time through interactive dashboards, and through observations by study staff. Coaches also observe some sessions live to monitor the quality of implementation. Coding sheets and manuals have been developed for observing the sessions; training is conducted using video sessions from prior sessions. Observations are conducted as part of standard implementation procedures.

Facilitators of *Thrive Professional Learning* complete fidelity checklists to track fidelity to program content, and overall ratings of the training experience. Each Professional Learning is co-facilitated, resulting in reliability ratings for each session.

6. Study Enrollment and Withdrawal

6.1 Inclusion Criteria

Site Selection Criteria

A total of 81 of these district schools with pre-K programs in high poverty NYC neighborhoods were selected for the study in late Spring 2017 by the NYC Department of Education (DOE), following a detailed methodology developed collaboratively by the NYC DOE and NYU Investigators.

To be eligible for the study, schools met the following criteria: a) have 2 or more PKFA classrooms; b) serve a high-need population and c) leaders ranked Thrive or Inspire as a first or second preference for the school. Sites that were currently implementing *ParentCorps* at the time of the randomization were not eligible for the study. “High need” was defined as follows: the site level percentage of students in poverty was above the median of the eligible pool; the site level percentage of students in poverty was in the second quartile of the eligible pool *and* two or more students were listed as living in temporary housing; *and/or* the site level percentage of students in poverty was in the first quartile of the eligible pool *and* 5 or more students were listed as living in temporary housing.

District schools were randomly assigned to one of three intervention conditions: Thrive Professional Learning + *ParentCorps* vs. Thrive Professional Learning vs. Inspire Professional Learning. All leaders in the 81 schools received communication from the NYC DOE and CEHD about the condition to which their school was randomized, and the programs and supports that their school would be receiving.

Participant Selection Criteria

The participants are Pre-K students and families attending the 81 district schools randomly selected for the study. The inclusion criteria are Pre-K students and families who are in the schools in 2019-2020. Only parents and students who are English or Spanish speaking will be eligible for participation in the study. In the 81 study schools, > 90% of the families are either English or Spanish speaking, and the intervention is offered to parents in English or Spanish. Parents will answer a few questions on the consent form to determine language eligibility (See Family Information Form (at consent)). If parents are not eligible for the study, based on language, they will be invited to contact study staff (via the Recruitment Flyer and the Key Information Form) to express interest in participating in a different survey. Parents will be surveyed in their preferred language for programmatic reasons, and these surveys will not be included as part of the research study. We are providing this option for equity reasons so that all interested parents will have an option to participate in some way.

6.2 Exclusion Criteria

Families in sites other than the 81 district schools randomized to this study are excluded. Additionally, parents or students who do not speak English and/or Spanish will not be eligible to participate. Teachers and principals from the 81 sites are not considered participants in the study of student and family outcomes. Note that teachers complete surveys on students, and provide consent for reporting on their perceptions of the students and family engagement, based on NYC DOE guidelines. Teachers however do not report on themselves and are not recruited as study participants in the traditional sense.

6.3 Vulnerable Subjects

This study includes families and Pre-K students. Therefore, since Pre-K students are included in the study, there are vulnerable subjects in this study.

6.4 Strategies for Recruitment and Retention

The 81 district schools were randomized in Spring 2017 in partnership with DECE at the NYC DOE. A total of 3,370 families across the 81 schools (20 sites assigned to Thrive Professional Learning plus ParentCorps, 21 assigned to Thrive Professional Learning and 40 assigned to Inspire Professional Learning) will be invited to participate in the study.

Recruitment:

Families of Pre-K students will be recruited to participate in the study in Fall 2019. Families will be invited to consent to their Pre-K students participating and to consent to their own participation in the study.

Recruitment of Principals/Sites

In November 2018, the NYC DOE Division of Early Childhood Education (DECE) sent an email notification to the 81 principals stating that their schools had been selected for this study and sharing a high-level summary of the outcomes of interest. In late Summer 2019, as part of internal communications within the DOE, partners at the NYC DOE will also send an email to principals to share that the study will be launching in Fall 2019.

Once IRB approval is obtained, the NYU study team will send principals an email (see Principal/Site Recruitment - Email) and “welcome packet” to understand more about our research team and how this study fits within the Thrive NYC initiative (e.g., FAQ co-developed with DECE [see Principal/Site Recruitment – FAQ], study-branded pens and notepads).

Then, NYU study staff will meet with the principals (in person, by phone or via Webex) to review study activities in detail and obtain permission to conduct the study in their school (see Principal Approval Signature Form). The NYU study team will maintain open lines of communication with principals by email, phone, regularly scheduled office hours (via Webex or phone), and on-site meetings as needed and as preferred by the principals. WebEx will be used as one option (instead of on the phone or in person) for principals to meet and talk with study staff. WebEx will be used for information sharing and recruitment of sites, and will not be used for recruitment of study participants. Principals can select to

use the voice only feature in WebEx, or can activate the video functionality. WebEx is provided as an option in the event that the principal would like to invite other school staff to the informational meeting, and will allow for audio or video conferencing. WebEx will be set up by the NYU study staff, using the NYU Langone log on. It will be set up so that the WebEx meeting can only be accessed and joined by the individuals who receive the meeting. The WebEx meeting will not be recorded.

Recruitment of Pre-K Families

Once IRB approval is obtained, Pre-K families will receive information about the study and be recruited in 2 phases: 1) initial outreach by DOE staff through channels in which they typically communicate with parents (see Phase 1 described below); and 2) outreach, recruitment and consenting by NYU Langone study staff (Phase 2 described below). Note that while school staff (principals, teachers, parent coordinators) may provide access to NYU staff to share recruitment materials (e.g., flyers) to parents, they will only support outreach by giving access to study staff; they will not be asked to represent the study, will not answer questions and they will not engage in consenting of families. Based on the NYC DOE IRB Guidance, we believe that this type of involvement by the DOE Outreach Team and school staff fits within standard practice of information-sharing and does not constitute engagement in human subjects research.

Outreach: Phase 1 will be conducted primarily by DOE personnel through the channels in which they typically communicate with families:

1a) DOE Outreach Team will share a message from DECE about the study, via 1-2 recorded phone message (“robo call”) to all pre-K parents in study schools and 1-2 text messages to pre-K families in study schools *who have given permission for DOE to contact them by SMS texting*. The DOE Outreach Team uses these communication methods in their standard practice with pre-K parents.

1b) Principals will be asked permission for study staff to hang up 1-2 study posters and provide opportunities for study staff to reach families (e.g., in person at pre-K orientation, emails from the school or other school events). We will offer a brief video (~2 minutes) for principals who wish to share about the study during school events or make it available on-site for parents who choose to watch. If parents approach school personnel with questions, school personnel will be asked to offer a contact card so that parents can reach out to the NYU study team to learn more about the study, or fill in their information on the contact card so that NYU study staff can contact them directly to share more about the study (See Family Recruitment – Poster; See Family Recruitment – Contact Card). School staff will not answer questions about the study or consent families.

1c) Principals and pre-K teaching teams (lead teachers, teaching assistants, parent coordinators) will be asked to provide opportunities for study staff to “backpack” (put in child’s backpack) recruitment materials, including study flyer, contact card, and folders with the Key Information Form, Consent Form, and branded pen, as with other materials they usually send home to parents. As needed, the NYU Study Team will provide on-site support to distribute these materials. (See Family Recruitment – Flyer, Key Information Form - Parent, Consent Form – Parent, Key Information Form - Parent).

Outreach and Recruitment: Phase 2 will be conducted by NYU Study Team by phone or email, however parents prefer, and on-site at schools.

2a) The NYU Study team will respond to calls or emails from interested parents, or contact parents who returned a contact card with a request to contact them. Parents will be provided with an NYU number to call and NYU study email on all outreach and recruitment materials.

2b) *In a subset of sites as needed to reach an adequate consent rate*, the NYU study team will engage with parents on-site however principals recommend, including setting up a table for parents who choose to stop by during drop off/pick up, setting up events in the school to engage parents, and speaking with parents attending pre-K orientation or other school events. Pre-K parents will be invited to speak with study staff to learn more about the research study, and to return the contact card if they want to be contacted by the study team.

Recruitment of Pre-K and Kindergarten Teachers:

Once IRB approval is obtained, the NYU study team will obtain permission from principals to contact teachers. Note that while principals may provide access to NYU study staff to share recruitment materials (e.g., flyers, consent forms) to teachers (including forwarding materials to teachers by email if the principal chooses), they will only support outreach by giving access to study staff; they will not be asked to represent the study, will not answer questions and they will not engage in recruiting or consenting of teachers. Principals may set up meetings for teachers and study staff, for informational purposes only, or invite study staff to meetings with teachers. Principals may also give study staff permission to contact teachers in their classroom and/or drop off materials in teachers' mailboxes.

The table below summarizes the outreach, recruitment and consenting procedures.

In support of parents' autonomy, and in recognition that adults process information in different ways, we will offer parents the opportunity to hear about the study at multiple times, in multiple ways, in both English and Spanish, so that parents can make an informed decision.	
Parent is introduced to the study multiple times, with the opportunity to access more information offered in a variety of ways:	<ul style="list-style-type: none"> • DOE Outreach Team "robo" call or text, included as part of standard outreach activities • On-site at school, via study poster, flyer, announcement from principal or pre-K teacher • Flyer sent home via back pack • On-site at school, by NYU study team, through school or study events, setting up tables during drop off/pick up
Parent may express interest in learning more by:	<ul style="list-style-type: none"> • Calling or emailing the NYU study team • Filling out the contact card and returning it to a sealed box at the school

Parent will receive detailed information about the study from:	<ul style="list-style-type: none"> • Receiving the Key Information Form and Consent Form in their child's backpack • NYU Study Team by phone or in person • Accessing study link online (sent via email or accessed directly via RedCap link on flyer)
Parent may choose to consent for their and their child's participation in the study by:	<ul style="list-style-type: none"> • Completing the consent form on paper and returning it to a sealed box at the school • Completing the consent form online (including authentication via RedCap). The online consent form is the same consent form as the paper consent form – it is uploaded in RedCap as a PDF document.

Note. All study materials will be available in English and Spanish, and the NYU Study Team has capacity to engage with parents in either language.

Retention:

Based on our previous work in New York City, we expect that approximately a 50% recruitment rate will be attained (approximately 1,700 parents and students). Once parents provide consent, parents and their children will participate for up to three years, from the beginning of Pre-K (September 2019) until the end of Grade 1 (August 2022). Parents will be informed prior to each assessment time point by mail, flyers via the school or email (if provided at time of consent).

6.4.1 Use of DataCore/Epic Information for Recruitment Purposes

DataCore and Epic will not be used for recruitment of participants for the purposes of this study.

6.5 Duration of Study Participation

Once parents provide consent for their Pre-K children to participate in the study, their children will participate for up to two years, from the beginning of Pre-K (September 2019) until the end of Kindergarten (June 2021). Students will be followed up until the end of Grade 5, as parents will consent to the use of students' school records until Spring 2026; note that students will not interact directly with the study staff for data collection after Spring 2021 (end of Kindergarten) and parents will not interact directly with study staff for data collection after Spring/Summer 2022 (Grade 1). (The PI has used similar procedures in prior studies in NYC schools).

Pre-K Teachers who complete surveys on students will participate for one year, during the Pre-K school year (2019-2020). Kindergarten teachers who complete surveys on students in the 81 schools will participate at one time point during the Kindergarten year (Spring 2021). Teachers are not considered traditional study participants for this study, as they are not reporting on themselves. Teachers are asked to report on students. As per DOE guidelines, anytime that teachers participate in research, either reporting on themselves or

as “informants”, they are required to complete a consent form to show their consent in filling out the questionnaires (regardless on the nature of the questions).

Parents who participate in the survey will directly participate for up to 3 years. Parents will participate in surveys twice in Pre-K, twice in Kindergarten and once in Grade 1. A detailed study timeline is depicted below in the “Study Procedures” section (see Figure 4, under *Section 8 – Study Procedures*). A table depicting the Schedule of Events is available in Appendix D (see the end of the document).

6.6 Total Number of Participants and Sites

A total of 81 sites that participate in Thrive and Professional Learning will be included; 20 sites providing Thrive and *ParentCorps*, 21 sites with Thrive Professional Learning alone and 40 sites with Inspire Professional Learning.

A total of 3,370 families of Pre-K students will be invited to participate across 81 sites. All students who are eligible and for whom parental consent is obtained (estimated 1,700; ~50% consent rate) will complete assessments in the school setting (twice in Pre-K and once in Kindergarten). We expect 1,700 parents will participate in the parent survey.

6.7 Participant Withdrawal or Termination

6.7.1 Reasons for Withdrawal or Termination

Parents will be free to withdraw from participation in the study (withdraw their child’s participation and/or own participation in the parent survey). Students can request to discontinue participation at any time. The decision to participate or not participate, or to withdraw, will not affect the parents’ or student’s experience in Pre-K, Kindergarten or Grade 1, and will not affect access to educational services.

6.7.2 Handling of Participant Withdrawals or Termination

To leave the study, participants will be asked to send a written notice to Laurie Brotman, Ph.D. at the following address: Department of Population Health, NYU School of Medicine, 227 E. 30th Street, Seventh Floor, New York, NY 10016, or email Dr. Brotman.

6.7.3. Premature Termination or Suspension of Study

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. If the study is prematurely terminated or suspended, the PIs will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Insufficient compliance with protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination of futility

7. Study Schedule

7.1 Screening

All families of Pre-K students will be invited for their children to participate in the study. Outreach to families will include all the methods indicated in the Recruitment section (see Section 6). Briefly: 1) school events and onsite at school by NYU study team; 2) flyers; 3) posters in the school; 4) “robo” calls or text messages from the site; 5) calls from the NYU study team (following parents’ request for contact). Parents will be provided with a consent form for their child’s participation in school-based assessments, parent surveys and the collection of student administrative records (see Consent Form - Parent). Parents will also be asked to consent to the use of family demographics and contact information (e.g., child date of birth) collected at the time of consent for study purposes (See Family Information Form – at consent). Parents will be able to provide written consent in the following ways, depending on principal’s and parent’s preferences and recruitment rates: 1) onsite at school by NYU study team; 2) e-consent; 3) backpacks or mail.

7.2 Enrollment: Study with Families and Students – Time 1 Study Visit (Fall 2019)

There will be 3,370 families in the 81 participating schools invited to participate. We expect to consent and enroll 1,700 families (~50% consent rate). Parents will be invited to provide written consent for their child’s and their own participation (Fall 2019).

Once written parental consent is obtained, Pre-K teachers will be asked by the NYU study team to complete surveys on the students for whom parental consent was obtained for participation in the study. Pre-K teachers will be provided with a consent form (to indicate voluntary participation in completing surveys on students) and will be asked to complete a short survey per consented student.

Parents will be invited to participate in a parent survey, in person or over the phone with NYU study staff, following consent, at a time that is convenient to parents. Following the survey, parents will provide their contact information (i.e., address or email) in order to receive compensation and to be followed up with up to two additional times. This contact information will be entered securely in RedCap, which is HIPAA compliant.

7.3 Intermediate Visit: Study with Families and Students – Time 2 Study Visit (Spring/Summer 2020)

Time 2 data collection with students will occur approximately 6-7 months after Time 1, in Spring 2020. This will include school-based assessments with students and teacher report on students. Pre-K students will be assessed in the school setting. Assessments will be scheduled in collaboration with school leadership and will be scheduled so as to not interfere with core instructional time. The study team will follow a verbal script to introduce the study to students and obtain their verbal assent (this will be documented on the form by the study team). School-based assessments with students will be completed on a tablet by the trained NYU study team. Procedures for teacher report on students and parent interviews are similar to Time 1. Additionally, parents will complete surveys over the phone during Summer 2020. Parent surveys will be similar to Time 1, except for the removal of

some demographic items, and the addition of a comparable number of items on contextual factors. Administrative data (for the Pre-K year) on Pre-K students will also be obtained, as available, from the NYC DOE.

7.4 Intermediate Visit: Study with Families – Time 3 Study Visit (Fall 2020)

Time 3 data collection with parents will occur in Fall 2020, when the students enter Kindergarten, approximately 12 months after Time 1. Parental verbal consent will be obtained for the survey. Parent surveys will be similar to Time 2. There is no data collection from students or teachers.

7.5 Intermediate Visit: Study with Families and Students – Time 4 Study Visit (Spring/Summer 2021)

Time 4 data collection with families and students will occur approximately 5 months after Time 3, when the students are completing Kindergarten. Only students who are in the 81 study schools at Kindergarten will be followed-up with school-based assessments and teacher report. Time 4 data collection will include school-based assessments of students. Student verbal assent will be obtained, similar to Pre-K. Kindergarten teachers of students will complete surveys on the students who remain in the 81 schools. Parents will participate in a parent survey, similar to Time 3. Administrative data (for the Kindergarten year) on the students will also be obtained, when available, from the NYC DOE.

7.6 Final Study Visit: Study with Families and Students – Time 5 Study Visit (Spring 2022).

Time 5 data collection with parents will occur approximately 12 months after Time 4, in Spring 2022, when the students are in Grade 1. Verbal consent will be obtained from parents. There is no data collection from students or teachers. Administrative data (for Grade 1) on the students will also be obtained, when available, from the NYC DOE.

Administrative data on the students will continue to be collected annually, from Spring 2023 (Grade 2) to Spring 2026 (Grade 5), for the students for whom parental consent is obtained. No study visits with students or parents will be conducted during this time period.

7.5 Withdrawal and Unscheduled Visits

We do not anticipate that there will be additional Visits for the study. If a participant (parent, student) selects to withdraw from the study, there will not be a scheduled Visit for the Withdrawal. If a parent selects not to be contacted for future surveys (Times 2 – 5), they will not be a scheduled visit for the study.

7.6 Participant Access to Study Intervention at Study Closure

Schools (20) assigned to Professional Learning plus *ParentCorps* will have participated in (and have therefore accessed) the intervention. Sites with Thrive and Inspire Professional Learning alone are not offered to participate in the intervention.

8. Study Procedures/Evaluations

8.1 Procedures

All families of Pre-K students in the 81 schools will be invited to participate in the study (both parent and pre-K child). Families will be recruited using all the methods indicated in the Recruitment section (Section 6.4). To summarize, families will receive information about the study and be recruited in 2 phases: 1) initial outreach for information sharing by the school staff to introduce the study and offer options for learning more about the study and 2) outreach, recruitment and consenting by NYU Langone study staff (Phase 2). Note that while the school staff (principals, teachers, parent coordinators) may share information and distribute materials (e.g., flyers) they will only engage in outreach, and will not engage in active recruitment and consenting of families. Families will learn about the study via: 1) “robo” calls or text messages from the NYC DOE Outreach Team, 2) posters in the school (see Family Recruitment – Poster), 3) flyers in backpacks (See Family Recruitment – Flyer; Contact Card), 4) phone calls or emails from the NYU Study Team (following parental request to be contacted), and, as needed, 5) on-site at school by NYU Study Team. The school staff will not actively recruit families and will not engage in consenting activities. They will share the recruitment documents and invite families to contact the NYU study team for additional information.

Parents will be provided with a Key Information Form and an informed consent form in person, via backpack, email or the mail (see Key Information Form – Parent; Consent Form - Parent). If parents receive the consents via backpack, email or the mail, they will be provided with a dedicated study contact person to contact (via call or email) should they have questions about the study or the consent form. Parents will be invited to contact the study staff directly to learn more about the study and get their questions answered (see Recruitment Flyer and Contact Card). Parents will also be provided with the link to the study information online, where they will be able to access the Key Information Form securely (in RedCap), review the consent form and consent online if preferred.

Parents will be invited to consent to their own participation in surveys, their child’s participation in school-based assessments, teacher ratings of their child, and the collection of student administrative records (including demographics such as child’s date of birth and race, indicators of child learning such as grades and standardized test scores, and indicators of child health such as height and weight). Parents will also be asked to consent to providing demographic information, at the time of consent, about their family (language, child’s date of birth, child’s gender) for study purposes. Finally, at the time of consent, parents will be asked to mark a box if they do not want the NYU Study Team to stay in touch with them about the study (in order to maintain contact between surveys) via a) text messages or b) mail.

Parents will be able to provide written consent. Written consent could occur in the following ways depending on parent’s preferences and recruitment rates: 1) onsite at school by the NYU study team; 2) back-packs (or mail if requested), with an invitation to contact study staff to learn more and/or to have an in-person meeting to discuss, and to return the consent form in a sealed envelope and drop off in sealed boxes in a secure location within

the school; and 3) e-consent, using RedCap (via a link provided through outreach methods and recruitment materials). More details on the consent procedures are below under Informed Consent - Section 13.

All Pre-K students for whom parental consent is obtained will participate in a school-based assessment, over two time points, during Spring 2020 (Pre-K) and Spring 2021 (Kindergarten year, if they are attending one of the 81 study school). The assessments will be conducted by trained NYU study staff. Student assessments will be scheduled with school leadership at a time that does not interrupt or interfere with core instructional time for students. The assessment will take one period (40-45 minutes) to complete. The NYU study team will complete the school-based assessment with students using a tablet. The activities on the tablet are games that measure children's attention, memory and learning about words and feelings. The NYU study team will also observe students' behavior during these tasks. In Pre-K only, the NYU study team will collect the students' height and weight at the end of the assessment (we have used similar procedures in prior studies). All assessments will be programmed in the tablet and all responses will be captured electronically. All student assessment data captured electronically will be collected and stored securely, and will not include personal identifying information (i.e., IP addresses, names, school names). Each student's record captured electronically will be identified by a unique identification number, generated randomly (see Section 13.4).

Pre-K and Kindergarten teachers in the 81 schools will also be asked, by the NYU study team, to complete short surveys on students for whom parental consent was obtained (twice in Pre-K and once in Kindergarten). Note that if students leave the 81 schools between Pre-K and Kindergarten, the study team will not be collecting teacher report on those students. Teachers will be asked to complete surveys on each student's learning, feelings and behavior at school. Teachers will be asked to provide consent for their participation in the study as reporters on student outcomes, as per NYC DOE procedures (see Pre-K Teacher Consent Form – Pre-K; Teacher Consent Form – Kindergarten). The surveys will not capture any personal identifiable information on the students or the teachers, and the questions do not include protected and personal health information (we used similar procedures in Protocols 12730 and s17-01812). Teachers will complete a paper consent, and return it to the study staff member. Teachers will complete surveys on each student on paper.

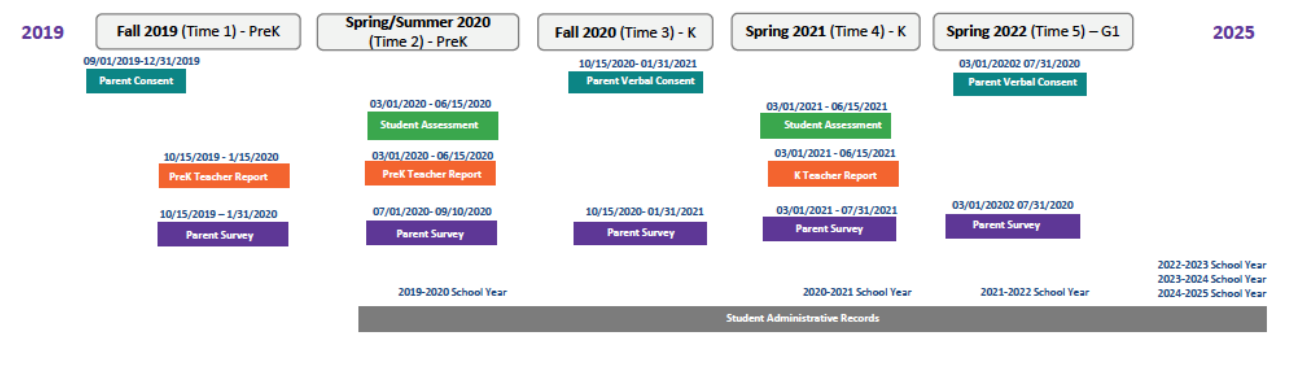
Parents who consent to participate in the parent survey will complete the survey with study staff over the phone, in their preferred language (English or Spanish) and at a time that is convenient for the parents. Parents can also request to complete the survey in person in their student's school. After an introduction referencing the study and the consent provided by the parent, parents will be asked to respond to questions about their parenting, family engagement and well-being, and their children's feelings and behaviors (see Introductory Script – Parent Survey). Parents provide written consent to complete surveys with NYU study staff twice in Pre-K (Fall 2019 and /Summer 2020) and a third survey in Kindergarten (2021), if selected. Parents will be invited to participate in two additional surveys, in order to fully understand children and families' well-being through Grade 1. Parents will be asked to

provide verbal consent to complete surveys in Fall of Kindergarten (2020) and Spring/Summer of Grade 1 (2022).

In Summer 2020, consented parents will be called to complete the survey (Time 2). A short introductory script will be read to review the study and key information from the consent form (see Parent Introductory Script – Parent Survey). After completion of the survey, parents will be asked whether they are interested in participating in an additional survey in Fall of Kindergarten. Interested parents will be contacted in Fall of Kindergarten; following verbal consent (see attached Verbal Consent Script – Parent Survey), parents will be asked to complete the survey over the phone (Time 3). In Spring/Summer 2021, at the end of Kindergarten, parents will be contacted and study staff will review the introductory script (see Parent Introductory Script – Parent Survey), followed by completion of the survey (Time 4). At the end of the survey, parents will be asked if they are interested in participating in one final survey at the end of Grade 1 (one year later). Interested parents will be contacted in Spring/Summer of Grade 1. Following verbal consent, parents will complete the survey over the phone with study staff. If parents cannot be reached at each time point (Times 2-4), they will be contacted by study staff at subsequent time points, and invited to participate, following the procedures above. This will give all parents who initially consented an opportunity to participate in the study through the end of Grade 1. In total, parents will complete up to 5 surveys over 3 years.

Following the surveys, parents will be asked to provide their e-email or mailing address, for the purposes of sending compensation for the interview. (See Introductory Script – Parent Survey).

Figure 5: Study Timeline



8.2 Questionnaire Administration

The student school-based assessments, teacher report on students, and parent survey are listed in the attached Measures (Appendix A-C).

Administrative Data

Administrative data will be requested from the NYC DOE when the student is in pre-K through fifth grade. Administrative data will only be obtained for students for whom parental consent is obtained for the release of administrative records (see Parent Consent Form). Administrative data will include child- and family-level demographic information (child date of birth, gender, race/ethnicity; home language; free or reduced lunch) and school-related information (attendance at school; standardized tests scores and grades, when applicable; whether the student is receiving special education services or has an Individualized Education Plan; height and weight, English Language Learner and dual language).

The record will include the Pre-K Screen data, kept as part of each Pre-K student's administrative record, as an indicator of school readiness (e.g., fine and gross motor development) and potential need for specialized resources or services. The DOE requires that a Pre-K screen is administered by teachers for each student within the first 45 days of school. Pre-K programs choose from one of three developmental screening tools that have been approved for use by the NYC DOE (i.e., Early Screening Inventory [ESI], Ages and States Questionnaire, Brigance Early Childhood Screens). The DECE provides materials and trainings for one of these standardized tests (ESI); the others do not require specialized materials or training. The developmental screening measures are valid and reliable screening tools to identify potential developmental delays and language supports needed for individual students. Once administered, teachers enter students' scores and are provided with cut-off scores to indicate if a student may require additional supports or programs. These data will be requested via the student record one time only in Pre-K. We are requesting the total raw score, or the raw score for each subscale (whichever is reported to DECE), and the "outcome" which provides an indicator about whether the child is developing within the typical range. Specifically, the Brigance Early Childhood Screen and the Early Screening Childhood Screen offer a total score; the Ages and Stages Questionnaire offer 5 separate subscale scores (Communication, Gross Motor, Fine Motor, Problem Solving, Personal/Social).

The administration record will also include information about the neighborhood in which the families live. Address data will provide the important information necessary to examine how children's neighborhood environments are related to their health and development and to examine the ways in which Thrive and ParentCorps impacts may differ for children who live in different types of neighborhoods. This information will be collected via the Research Alliance and DECE in order to characterize neighborhoods as accurately and precisely as possible without collecting addresses.

Based on their agreement with the NYC DOE, the Research Alliance for New York City Schools has informed about families' administratively defined neighborhoods (e.g., zip code). The Research Alliance will construct variables of neighborhood characteristics by pulling publicly available data about these neighborhoods and merging it into their study file. For example, the Research Alliance will define students' neighborhoods based on their zip code. They will then access publicly available data (e.g., Census data) which provides a variety of information about the characteristics of these zip codes (e.g., percent poverty, percent high school graduates) and merge this information into their study file. The

Research Alliance will then share the file with the NYU study team. The study team will not obtain student's address as part of the administrative record. The Research Alliance will define a student's neighborhood, link with publicly available data and then share the neighborhood variables with the study team. The study team will not obtain student's address as part of the administrative record. These data will be transmitted securely. The Research Alliance for New York City Schools, led by Co-Investigator Dr. Jim Kemple, is based at NYU. The Research Alliance conducts rigorous, applied research in collaboration with policymakers, educators and other stake holders. It also maintains an archive of longitudinal data and has an MOU with the NYC DOE to obtain and share data, following approvals, with the research community. The NYU study team has an agreement with the Research Alliance for this scope of work.

There have been major advances in strategies to capture "neighborhood" which involve defining neighborhood boundaries using an "ego centric buffer" in which the neighborhood is defined as a certain distance around the child's home. In addition to the neighborhood variables obtained via the Research Alliance, in order to use novel methodological techniques to characterize students' neighborhoods, DECE will prepare a file containing the geocoded x,y coordinates that are already maintained as part of their system (ATS). DECE will use the x,y coordinates to construct child-centric neighborhoods for each child. For example, a 1/2 mile radial buffer around the x,y coordinates. Neighborhood characteristic variables will then be constructed by linking these child-centric neighborhoods with publicly available data (e.g., Census data). For example, a neighborhood-level measure of percent poverty based on Census data will then be constructed by proportionally interpolating values based on the census geographies in each child's defined neighborhood (values across census geographies will be weighted proportionate to their area within the defined neighborhood buffer; Duncan et al., 2012). DECE will include these new neighborhood-level characteristic variables in their study file. DECE will remove x,y coordinates from the study file. This final file will thus contain the neighborhood characteristic variables for each student. The final file will not contain x,y coordinates or any variable that could be used to reconstruct the x,y coordinates. These neighborhood characteristic variables cannot be re-connected to the x,y coordinates. This final file will be securely transmitted to the NYU study team.

Together, this information about students' administrative neighborhoods (from Research Alliance) and child-centric neighborhoods (from DECE), obtained without sharing of student addresses, will allow for a nuanced understanding of the role of children's neighborhood characteristics in healthy development.

During the consent process, parents will be asked to provide demographic information on their family and their address for the study. Specifically, parents will provide information on their child's and their own language (to determine eligibility, to describe the sample, and following best practice for assessing bilingual children), child's date of birth (to describe the sample and score assessments against age-normed guidelines), and child's gender (to describe the sample and for analyses).

School-based Assessment with Students

For the school-based assessments with students for whom consent is obtained, the NYU study team will administer activities with students using tablets (such as an iPad). The assessments do not contain any personal health information and do not capture or record any personal identifiable information (PII).

Academic Skills (Language)

Receptive One-Word Picture Vocabulary Test (ROWPVT) – 4th edition. The Receptive One-Word Picture Vocabulary Test (ROWPVT – 4; Martin & Brownell, 2010) and the Spanish-Bilingual Edition (SBE) are norm-referenced measures that assess a child's receptive language. The assessor says a word in English or Spanish and the child is shown four images and asked to choose the one image out of the four that represents the word the assessor said. The assessment takes 10-20 minutes and has been normed from ages 2 to 80.

Social Emotional Learning (Self-Regulation - Executive function)

Hearts and Flowers. Hearts and Flowers (Davidson, Amso, Anderson, & Diamond, 2006) is an executive function task and is composed of three sections of increasing difficulty: a congruent, an incongruent, and a mixed section. On mixed trials, children are presented with 33 test trials, with a stimulus span of 2500 milliseconds, where both hearts (press on same side) and flowers (press on opposite side) rules are presented and children must follow the rules for each.

Dimensional Change Card Sort (DCCS). The Dimensional Change Card Sort (Gershon et al., 2013; Zelazo et al., 2013; is used to measure executive functioning, and in particular, cognitive flexibility and set shifting. Children are presented with a series of cards depicting images that vary along two dimensions: color and shape (e.g., boats and rabbits, colored white and yellow). Children are first asked to sort the cards by one dimension (color). After they do this for several trials, they are then asked to sort the cards by the other dimension (shape). Ability is measured by the extent to which the children can shift to sorting by the second dimension accurately.

Pencil Tap. In the Pencil Tap task (Diamond & Taylor, 1996), children are asked to tap on a table twice with a pencil when the experimenter taps once, and once when the experimenter taps twice. This task requires children to inhibit a natural tendency to mimic the action of the experimenter while remembering the rules, assessing inhibitory control, attention skills, and working memory. Scores are based on the proportion of trials children answer correctly out of 16. This task has demonstrated robust psychometric properties, has been included in efficacy trials with preschool children, and has been shown to be predictive of mathematics ability in a study with low-income Head Start children (Blair & Razza, 2007).

Preschool Self-Regulation Assessment (PSRA). Upon completion of child direct assessments, the assessor will fill out a brief report describing the child's levels of attention, emotion, and behavioral regulation demonstrated by the child during all of the assessment tasks, using the Preschool Self-Regulation Assessment (PSRA) Assessor Report (Raver et

al., 2009; Smith-Donald, Raver, Hayes, & Richardson, 2007). The PSRA is a 28-item psychometrically valid and reliable measure providing a measure of children's emotions, attention, and impulsivity throughout the assessor-child interaction on a 1-4 rating scale.

Social Emotional Learning (Emotional)

Assessment of Children's Emotional Skills (ACES). The ACES (Schultz & Izard, 1998) task is a commonly used measure of children's perception, labeling, and matching of emotions (Izard et al, 2001; Mostow et al., 2002; Schultz, Izard, & Bear, 2004; Trentacosta & Izard, 2007). Children are presented with a series of photographs of children making happy, sad, mad, scared, or ambiguous facial expressions. Pictures include males and females from diverse racial/ethnic backgrounds. For each photograph, children are asked to name the emotion expressed in the face. Photographs are taken from the CAFÉ set of faces (LoBue & Thrasher, 2015; LoBue, 2014).

Emotion Recognition Questionnaire (ERQ). The ERQ (Ribordy, Camras, Stafani, & Spacarelli, 1988) measures children's ability to identify emotions that are elicited in a series of brief scenarios. Sixteen scenarios that elicit happy, sad, mad, or scared emotions are presented to children, along with black and white line drawings to aid with comprehension (e.g., Johnny's little brother broke his toy on purpose, Susie has a birthday party with lots of cake, fun games, and presents). Children are asked to name the emotion the main character would be feeling in that situation. Alternatively, children may point to a face expressing that emotion. Photographs are taken from the CAFÉ set of faces (LoBue & Thrasher, 2015; LoBue, 2014).

Dot Probe. The dot probe task is designed to measure a child's ability to control their attention when presented with emotional stimuli (pictures), versus become distracted by emotional stimuli (Blair & Raver, 2014). For each dot probe trial, two pictures are flashed on a screen simultaneously: (a) two neutral images on both sides of the screen (e.g., chair, lamp, cup) or (b) a neutral image on one side of the screen plus an image that evokes a negative emotion on the other side of the screen (e.g., snake, wolf, car crash). After the images are presented, a dot appears on the screen, and children are instructed to press a key on the side of the keyboard corresponding to the side of the screen on which the dot appears. Reaction times are calculated for trials when the dot is on the same side as the emotional image, and when the dot is on the opposite side. Children who are more easily distracted by emotional stimuli will take longer to react when the dot is on the opposite side of the screen (i.e., when the dot is behind the neutral image, and not the emotional image). Children who are better at controlling their attention in the face of emotional stimuli will show more similar reaction times regardless of whether the dot appears behind the neutral image or the emotional image.

Height and Weight

Body Mass Index (BMI). Children's height and weight will be measured in order to calculate BMI in Pre-K. At the end of the assessment, study staff will collect children's height and weight using standardized procedures. Study staff will use a stadiometer to collect height

and an electronic scale (provided by the study) to obtain children's weight. The protocol requires the study staff to take up to 3 measurements of each in order to ensure validity of the results.

Parent Survey

Parenting

Parenting Practices Scale (PPS; Strayhorn & Weidman, 1988). The PPS is self-report measure that assesses parenting behaviors. This instrument was developed and validated with a sample of low income families with children enrolled in Head Start programs. The instrument's authors found the scale to demonstrate both good test-retest reliability and internal consistency ($\alpha = .79$) as well as evidenced validity when the scale was compared to videotaped observation of parent behavior (Strayhorn and Weidman 1988). Spanish versions of the scale have demonstrated adequate reliability and validity with Latino immigrant populations (e.g., Calzada and Eyberg 2002; Crossley and Buckner 2012; McCabe, Mechammil, Yeh & Zerr, 2016) as well as with African American and non-Latino Caucasian populations (Crossley and Buckner 2012).

Mindfulness in Parenting Questionnaire (MIPQ; McCaffrey, Reitman & Black, 2017). Mindful discipline will be assessed using the "mindful discipline" subscale of the MIPQ. The MIPQ is a measure of mindful parenting for mothers and fathers of both children and adolescents, ranging in age from 2- to 16-years old. The subscale consists of fifteen items rated on a four-point likert scale (1 = infrequently, 4 = almost always). Item content reflects non-reactivity in parenting, parenting awareness, and goal-focused parenting. Psychometric analyses conducted by the authors indicate this subscale has good reliability ($\alpha=.84$).

Interpersonal Mindfulness in Parenting (IEM-P). The IEM-P includes items regarding three domains: awareness and present-centered attention regarding parents' experience during interactions with their child; openness and non-judgmental stance towards the child's thoughts and emotions; and low reactivity to culturally-accepted children's behavior. Four items of the scale are used in this study. Parents are asked to respond to items on a four-point scale, ranging from Never True = 1 to Often True = 4.

The Parental Engagement of Families Questionnaire [PEFL; McWayne, Foster & Melzi, 2013] is a 43-item Likert-type measure of parental engagement designed for and validated with Latino Head Start families. The 43-item PEFL contains items reflecting the following dimensions: Foundational education($\alpha= .87$) consists of 20items designed to reflect parents' efforts to teach their children "the basics"; supplemental education($\alpha= .81$) comprises 12 items designed to reflect parents' efforts to provide stimulating experiences beyond "the basics"; school participation($\alpha= .79$) contains 8 items designed to capture parents' active participation in school-based activities; and future-oriented teaching($\alpha= .73$)

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includes 3 items designed to reflect parents' efforts to socialize their children around the importance of education. The items for each dimension were administered with a 4-point rating scale (i.e., 1 =never/nunca, 2= rarely/rara vez, 3=sometimes/algunas veces, 4=frequently/frecuentemente).

Child Routines Inventory (CRI; Sytsma, Kelley, & Wymer, 2001). The Daily Living Routines subscale of CRI will be used. The CRI is a parent-report measure of commonly occurring routines in school-aged children. The daily living routines subscale consists of 11 routines centered around activities of daily living such as morning routine and a bedtime routine. The subscale has good internal consistency ($\alpha = .81$) and good test-retest reliability ($r = .86$).

Parent Evidence-Based Strategies Scale. Parent evidence-based strategies scale (17 items, self-report 1-5 point scale) assess the frequency that parents apply a range of evidence-based parenting strategies (e.g., behavioral management, promotion strategies). The scale is adapted from The Teacher Strategies Questionnaire (TSQ) (Webster-Stratton et al. 2001).

Family and Provider/Teacher Relationship Quality (FPTRQ; Kim et al., 2015). Family Engagement will be measured with the FPTRQ tools, which assess four constructs: attitudes, knowledge, practices and environmental features. Each of these constructs consists of several elements; the exception is Knowledge, which includes only one element--Family-Specific Knowledge. There are four elements in the Attitudes construct: Respect, Commitment, Openness to Change, and Understanding Context. The five Practices elements include Communication, Collaboration, Responsiveness, Connecting to Services, and Family-focused Concern. The Environmental Features construct consists of five elements: Welcoming, Communication Systems, Culturally-Diverse Materials, Information about Resources, and Peer-to-Peer Parent Activities. The FPTRQ was developed and validated with racially and ethnically diverse families in a range of early childhood education settings (Kim et al, 2015).

Parent Well-Being

Patient Health Questionnaire (Kronke, Spitzer & Williams, 2001). The PHQ-9 is one of the most validated tools in mental health and can be used to screen for depression and anxiety. Items are rated on a 4-point scale, ranging from 0 = not at all to 3 = nearly every day. For this study, 4 items will be used.

Center for Epidemiological Studies – Short Depression Scale (CESD-10). This scale is a self-report measure of depressive symptoms. Parents respond to 10 items on a five point Likert scale. There are eight items that measure symptoms of depression frequency and two that measure positive affect and that are reverse coded to fit the measurement scale model. The CESD-10 produces a continuous score that dichotomizes at eight points (equivalent to the full CESD of 16 points) for classifying subjects with clinically relevant symptoms of depression. The CES-D-10 is a 10-item Likert scale questionnaire assessing depressive symptoms in the past week. It includes three items on depressed affect, five

items on somatic symptoms, and two on positive affect. Options for each item range from “*rarely or none of the time*” (score of 0) to “*all of the time*” (score of 3). Scoring is reversed for items 5 and 8, which are positive affect statements. Total scores can range from 0 to 30. Higher scores suggest greater severity of symptoms. Reliability for this scale across diverse samples has been adequate 0.69–0.89.

Financial Stress. To examine the degree to which parents worry about their finances, 8 questions will be asked to form a composite measure of financial stress. Parents respond to each item on a 5-point Likert scale. This measure has shown strong internal reliability with diverse samples of parents in the U.S. ($\alpha = .89$; Gilbert, Spears Brown, & Mistry, 2017; Mistry et al. 2002).

Parenting Strain (Caripiano & Kimbro, 2012). Consistent with previous research (Carpiano & Kimbro, 2012), our measure of parenting strain is constructed from four items that asked respondents to rate how much they agree with the following statements: “Being a parent is harder than I thought it would be,” “I feel trapped by my responsibilities as a parent”, “I find that taking care of my child/children is much more work than pleasure,” and “I often feel tired, worn out, or exhausted from raising a family.” Responses to each question range from 1 (completely false) to 5 (completely true). Responses are summed so that higher numbers indicate more parental strain. The resulting measure ranges from 4 to 20. Cronbach’s alpha for these four items was 0.70.

The Hope Scale (Synder et al., 1996) will be used as a measure of parental efficacy. The measure is intended to assess agency (e.g., “belief in one’s capacity to initiate and sustain actions”) and pathways (e.g., “belief in one’s capacity to generate routes”) to achieve goals. Parents indicated their agreement with six items. Previous studies using this scale as an assessment of self-efficacy have found good scale reliability ($\alpha = .83$) with a diverse set of parents. See Mistry et al., 2002.

The Multidimensional Scale of Perceived Social Support (MSPSS; Zimet et al., 1988). The MSPSS is a 12-item measure of perceived adequacy of social support from three sources: family, friends, & significant other; using a 5-point Likert scale (0 = strongly disagree, 5 = strongly agree). Four items from the scale will be used to assess support from family and friends.

PROMIS-10. The PROMIS is a tool that can be used to evaluate physical, mental, and social health of adults and children. PROMIS has created item banks (a collection of questions measuring the same construct that can be administered in short forms). The short form used for the purposes of this study is a 10-item survey. The items cover general well-being (“In general, how would you rate your satisfaction with your social activities and relationships”, “In general would you say your quality of life is”, and “In general would you say your health is”). Participants are asked to respond on a 5-point scale, ranging from 1 (Poor) to 5 (Excellent). The PROMIS was developed by scientists working with the National Institutes of Health, and the measure has strong validity.

PROMIS – 4 Sleep Disturbance. This is a 4-item questionnaire assessing the quality of adult sleep. Participants are asked to respond on a 5-point scale ranging from 1 (not at all) to 5 (very much) to questions regarding their sleep quality (“In the past 7 days my sleep was refreshing”).

Context

Perceptions of Neighborhood Safety. Five items from the Exposure to Violence interview (Earls, Brooks-Gunn, Raudenbush, & Sampson, 1994) will be used to construct a measure of perception of safety in their neighborhoods. This scale has shown adequate reliability ($\alpha = .73$) and validity with families from diverse ethnic and immigrant backgrounds (see Barajas-Gonzalez & Brooks-Gunn, 2014).

Discrimination Fear. Four items from the Heightened Vigilance Scale (from the Chicago Community Adult Health Study) will be used to assess parental vigilance. This scale has shown adequate reliability ($\alpha = .72$) and construct validity in studies of vigilance and health outcomes (Hicken, Lee, Ailshire, Burgard, & Williams, 2013; Hicken, Lee, & Hing, 2018; Williams, 2016). Eight items from the Discrimination interview (Earls, Brooks-Gunn, Raudenbush, & Sampson, 2000-2002; PHDCN) will be used to assess parent’s worry about discrimination. This scale has demonstrated adequate reliability (α range .737-.804) in samples with Black, Latino and White parents of varied immigrant backgrounds (Herda, 2016; Herda & McCarthy, 2018).

Coronavirus Impact Scale. This scale, developed by Kaufman and Stoddard 2020, includes 9 items to rate how COVID-19 has changed an individual’s life, in domains such as finance, routines, medical access, and social supports. The measure was modified to include questions relevant to distance learning experiences and parents’ perception of child well-being and parenting stress. It was provided as one of measures recommended by the NIH Office of Behavioral and Social Sciences Research to assess COVID-19 relevant behavioral and science domains for research. Parents will be asked questions on this measure from Time 2 – Time 5.

Food Insecurity. The U.S. Household Food Security Survey Module: Six-Item Short Form (Economic Research Service, USDA) will be used to assess household food insecurity. Food insecurity has increased due to the COVID-19 pandemic, especially in households with young children (Bauer, 2020; Jyoti, Frongillo & Jones, 2005), and is a relevant contextual stressor. Parents will be asked questions on this measure from Time 2 – Time 5.

Community Cohesion – Project of Human Development in Chicago Neighborhoods (PHDCN). Participants report their agreement with 5 statements indicative of neighborhood cohesion, with responses ranging from 1 = *strongly disagree* to 5 = *strongly agree*. Responses are averaged ($\alpha = .75$), such that higher scores indicated greater neighborhood cohesion. This measure has been shown to be associated with better mental health among 5–11-year-olds ([Xue, Leventhal, Brooks-Gunn, & Earls, 2005](#)), and protective against

elevated externalizing problems for African American youth who experience racial discrimination ([Riina, Martin, Gardner, & Brooks-Gunn, 2013](#)).

Demographics. Parents will also be asked to provide demographic information on their family and children. The demographic form includes questions about parents' and children's race, ethnicity and gender, family composition (i.e., number of children in the home), languages spoken at home and teacher's language (if child is bilingual). It also includes questions on parents' background (i.e., marital status, and education status, and other family contextual information (i.e., income). Note that some of the demographic items will only be asked at Time 1 (these are indicated with an asterisk on the Appendix). Demographic items related to COVID-19 were also added (e.g., if a parent is an essential worker, household composition during COVID-19).

Parent Report on Child Well-being (Feelings and Behavior at Home)

The Social Competence Scale - Parent Version is a 12-item measure that assesses a child's prosocial behaviors, communication skills, and self-control. The Social Competence Scale was created for the Fast Track Project. Some items on the Scale were adapted from the Kendall and Wilcox (1979) and Gersten (1976) assessments. New items were also developed. The Parent Version of the Scale contains a subset of the items on the Teacher Version. Each item on this Scale states a behavior that a child may display in a social setting. Examples of statements include: "Your child can give suggestions and opinions without being bossy" and "Your child can calm down when excited or all wound up." The parent assesses how well each statement describes the child. Responses are coded on a five-point Likert scale ranging from zero (Not at all) to 4 (Very Well). The Scale contains two subscales: Prosocial/Communication Skills (Items 4, 7, 9, 10, 11 and 12) and Emotional Regulation Skills (Items 1, 2, 3, 5, 6, and 8). In addition to the subscale scores, a total score on the 12 items is also reported.

NIH Toolbox Emotion Battery. Parents will report on three scales from the NIH Toolbox Emotion Battery: Anger Parent Report, Fear-Over Anxious Parent Report, Fear – Separation Anxiety, and Sadness Parent Report (Gershon, Wagster, Hendrie, Fox, Cook, & Nowinski, 2013). These measures were designed for children ages 3 – 7. The Anger Parent Report includes 9 items which measure attitudes of hostility and cynicism often associated with experiences of frustration impeding goal-directed behavior. The Fear-Over Anxious Parent Report includes 6 items measuring symptoms of anxiety that reflect autonomic arousal and perceptions of threat. The Fear-Separation Anxiety Parent Report includes 7 items measuring symptoms of anxiety that reflect autonomic arousal and perceptions of threat. The Sadness Parent Report includes 7 items measuring low levels of positive affect; comprised of symptoms that are primarily affective (poor mood) and cognitive (negative perceptions of self, the world, and the future) indicators of depression.

The Pediatric Symptom Checklist (PSC). Parents will report on the attention problems subscale of the PSC (Jellinek, Murphy, Little et al., 1999; Jellinek, Murphy, Robinson et al., 1988). It is a well-known measure that is frequency utilized to screen psychosocial functioning in children 4-18 years of age. Parents are asked to rate each symptom with 0 =

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never, 1 = sometimes, and 2 = often. Higher scores indicate greater risk. The PSC has high sensitivity (80-95%) in detecting behavior problems.

Child Health: Parents will report on child's sleep practices, child's screen time, and child's fruit and vegetable intake. Specifically, parents will be asked about child's bedtime and wakeup time during the week and on weekends (7 items) and 4 questions about the child's sleep disturbances from the PROMIS-4 sleep disturbance questionnaire. Parents will also report about child's TV time (1 items) and screen time (2 items) and child's fruit and vegetable intake (2 items). Parents will also be asked to report on their children's height and weight, through 4 items.

Teacher Report/Survey on Students

Child Well-being (Feelings and Behavior at School) and Learning

Social Competence Scale. Teachers will report on, a 25-item scale developed for the Fast Track prevention trial to assess emotion regulation, prosocial communication, and academic skills in young children (CPPRG, 1992). Teachers rate the extent to which each item is characteristic of the child on a 5-point scale (0= Not at All, 4 = Very Well). A recent study provides strong evidence of the salience of early social competence; kindergarten teacher ratings on this scale predicted high school graduation and other key young adult outcomes, adjusting for numerous covariates including poverty, family life stressors, and early academic skills (Jones, Greenberg, & Crowley, 2015).

Student-Teacher Relationship. The Student-Teacher Relationship Scale - short form is a teacher-report instrument designed for teachers of children between the ages of 3 and 12 which measures a teacher's perception of conflict and closeness with a specific child. The STRS includes 15 items has been normed on more than 1500 students and 275 teachers and has been shown to be psychometrically reliable and valid (Pianta, 2001).

School-Readiness Questionnaire. Teachers will report on a 14-Item measure of student self-regulation and learning motivation (Bierman, Nix, Heinrichs, Domitrovich, Gest, Welsh, & Gill, 2014). Items are rated on a 6-point scale with response options ranging from strongly disagree to strongly agree ($\alpha = .96$).

Sleepiness. Teachers will report on a 3-item measure on children's sleepiness in the classroom.

Self-Regulation. Teachers will report on a 12 item measure of child regulation using the Children's Behavior Questionnaire (Rothbart, Ahadi, Hershey & Fisher, 2001). This measure provides three factors: Attentional Focusing and Inhibitory Control. It is widely used in developmental research.

9. Safety and Adverse Events

9.1 Definitions

The definitions below are included in the protocol as part of the template provided by the NYU School of Medicine IRB.

Unanticipated Problems Involving Risk to Subjects or Others

Any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in nature, severity, or frequency (i.e. not described in study-related documents such as the IRB-approved protocol or consent form, the investigators brochure, etc.)
- Related or possibly related to participation in the research (i.e. possibly related means there is a reasonable possibility that the incident experience, or outcome may have been caused by the procedures involved in the research)
- Suggests that the research places subjects or others at greater risk of harm (including physical, psychological, economic, or social harm).

Adverse Event

An **adverse event** (AE) is any symptom, sign, illness or experience that develops or worsens in severity during the course of the study. Intercurrent illnesses or injuries should be regarded as adverse events. Abnormal results of diagnostic procedures are considered to be adverse events if the abnormality:

- results in study withdrawal
- is associated with a serious adverse event
- is associated with clinical signs or symptoms
- leads to additional treatment or to further diagnostic tests
- is considered by the investigator to be of clinical significance

Serious Adverse Event

Adverse events are classified as serious or non-serious. A **serious adverse event** is any AE that is:

- fatal
- life-threatening
- requires or prolongs hospital stay
- results in persistent or significant disability or incapacity
- a congenital anomaly or birth defect
- an important medical event

Important medical events are those that may not be immediately life threatening, but are clearly of major clinical significance. They may jeopardize the subject, and may require intervention to prevent one of the other serious outcomes noted above. For example, drug overdose or abuse, a seizure that did not result in in-patient hospitalization, or intensive treatment of bronchospasm in an emergency department would typically be considered serious.

All adverse events that do not meet any of the criteria for serious should be regarded as ***non-serious adverse events***.

Preexisting Condition

A preexisting condition is one that is present at the start of the study. A preexisting condition should be recorded as an adverse event if the frequency, intensity, or the character of the condition worsens during the study period.

General Physical Examination Findings

At screening, any clinically significant abnormality should be recorded as a preexisting condition. At the end of the study, any new clinically significant findings/abnormalities that meet the definition of an adverse event must also be recorded and documented as an adverse event.

Post-study Adverse Event

All unresolved adverse events should be followed by the investigator until the events are resolved, the subject is lost to follow-up, or the adverse event is otherwise explained. At the last scheduled visit, the investigator should instruct each subject to report any subsequent event(s) that the subject, or the subject's personal physician, believes might reasonably be related to participation in this study. The investigator should notify the study sponsor of any death or adverse event occurring at any time after a subject has discontinued or terminated study participation that may reasonably be related to this study. The sponsor should also be notified if the investigator should become aware of the development of cancer or of a congenital anomaly in a subsequently conceived offspring of a subject that has participated in this study.

9.2 Recording of Adverse Events

The Investigators will be responsible for recording and reporting adverse events and unanticipated problems, as defined by the NYU School of Medicine IRB. The Investigators will ensure that they are knowledgeable of the definitions for safety and adverse events. All adverse events occurring during the course of the study will be recorded. The current study includes surveys and interviews, and does not involve diagnostic procedures or clinical treatment. Should an adverse event occur, the event will be recorded and followed until resolution, stabilization or until it has been determined that participation in the study was not the cause of the adverse event. Serious adverse events that are ongoing at the end of the study will be followed up to determine the final outcome.

9.3 Reporting of Serious Adverse Events and Unanticipated Problems

Any serious adverse event that may occur after the study period, and considered to be possibly related to study participation, will be recorded and reported promptly. Adverse events will be reported to the IRB, following the protocol for a written narrative, and submission requirements provided by the IRB. The Investigators will submit reports promptly, but no later than 5 working days, from the time that the investigators become aware of the event for:

1) *Unanticipated problems including adverse events* that are unexpected and related:

- Unexpected: An event is “unexpected” when its specificity and severity are not accurately reflected in the protocol-related documents, such as the IRB-approved research protocol and the current IRB-approved informed consent document.
- Related to the research procedures: An event is related to the research procedures if in the opinion of the principal investigators, the event was more likely than not to be caused by the research procedures.
- Harmful: Either caused harm to subjects or others, or placed them at increased risk.

2) *Other Reportable events*:

- Complaint of a research subject when the complaint indicates unexpected risks or the complaint cannot be resolved by the research team.
- Protocol deviations or violations (includes intentional and accidental/unintentional deviations from the IRB approved protocol) for any of the following situations: one or more participants were placed at increased risk of harm; the event has the potential to occur again; the deviation was necessary to protect a subject from immediate harm.
- Breach of confidentiality
- Incarceration of a participant when the research was not previously approved under Subpart C and the investigator believes it is in the best interest of the subject to remain on the study.
- New Information indicating a change to the risks or potential benefits of the research, in terms of severity or frequency.

9.3.1 Investigator reporting: notifying the IRB

The reportable events noted above will be reported to the IRB using a Reportable New Information submission and will include a description of the event with information regarding its fulfillment of the above criteria, follow-up/resolution, and need for revision to consent form and/or other study documentation. Copies of each report and documentation of IRB notification and receipt will be kept in the Investigators' study file.

10. Study Oversight

The Principal Investigators will be responsible for all aspects of the study and will oversee the safety of the study at the site. Safety monitoring will include careful assessment and appropriate reporting of adverse events as noted above. It will also include regular data monitoring, overseen by Co-PI Troxel.

11. Statistical Considerations

11.1 Study Hypotheses

We hypothesize that families and students in ParentCorps will have better social emotional learning and academic skills, and effective parenting, compared to those not engaged in ParentCorps.

11.2 Sample Size Determination

We have an eligible population of 3,370 Pre-K families in the 81 participating schools. We conservatively estimate a ~50% consent rate, based on our experience conducting similar studies in the past, which will yield approximately 1,700 families who will consent for their students to participate and who will complete surveys. With families divided approximately evenly by intervention group, this sample size yields 80% power to detect between-group differences of approximately 0.43 standard deviations in continuous outcomes, using a two-sided, 0.05-level test.

11.3 Statistical Methods

Analyses of Survey Data

Preliminary analyses Preliminary analyses will focus on the psychometric and distributional properties of survey measures. Members of our investigative team have previously used all of the measures included in the study and have encountered no serious psychometric problems with any of them. Nevertheless, preliminary analyses will examine any abnormal distributions, outliers, or unusual patterns of missing data. Our preliminary analyses will also include estimating general linear models to determine whether there are pre-intervention differences among the Thrive Professional Learning plus *ParentCorps*, Thrive Professional Learning and Inspire Professional Learning groups for any important baseline demographic characteristics that we may need to adjust for in outcome analyses.

Sample attrition and missing data

A number of strategies will be used to minimize attrition including providing compensation for teachers and families to complete the measures, alternative options to completing the parent survey (e.g., onsite), and follow-up reminders to minimize data missing due to schedule conflicts and other barriers. We will also stay in contact with families with monthly messages or post cards. Despite these efforts, based on our prior experience we anticipate family attrition rates of approximately 10-12% (170-200 families). We will conduct analyses to determine whether the attrition that does occur differs by intervention condition or site characteristics. If we find differential attrition, we will adjust for such factors in our analytic models. We may also use propensity score matching to statistically re-weight our samples. We expect sample attrition will account for most of our missing data. If we are missing more than 15% of our data on any outcome measure, however, we will estimate our models using full information maximum likelihood, or we will conduct multiple imputation (Schafer, 1997).

Main analyses

Tests of our study hypotheses require consideration of the hierarchically nested nature of the data that will be obtained (students nested within schools). Hierarchical Linear Modeling (HLM) techniques using HLM 6.06 (Raudenbush & Bryk, 2002; Willett & Sayer, 1994) or other mixed effects models will therefore be employed to estimate the impact of Thrive Professional Learning plus *ParentCorps*, versus Thrive Professional Learning or Inspire Professional Learning on family and student outcomes. Mixed models are well suited for such analyses as they enable examination and modeling of patterns of both random and

non-random missing data, and can accommodate unequal numbers of teachers and families within centers.

12. Source Documents and Access to Source Data/Documents

The primary data collection for the study with families and students are school-based assessments (collected via tablet by the NYU study team), teacher report on child outcomes (collected on paper surveys by NYU study team) and parent surveys (obtained via phone interview or in person by NYU study team; collected on paper or electronically and securely via RedCap). All administrative data from the NYC DOE will be available electronically (i.e., excel or statistical software).

All data will be entered, stored and tracked in RedCap, which is HIPAA compliant. RedCap can be accessed by a unique user name and password (i.e., NYU Langone Kerberos ID). Access to study records will be limited to NYU study team. All data with identifiable information (name, address, date of birth) will be entered separately to the study data, with higher restrictions of access to study staff. All data files used for analyses will be securely saved in a network drive that includes password protection, limited access to data by staff and different levels of access depending on the person's position on the research team.

The majority of the data will be collected electronically. For the data coded on hard copy (e.g., teacher report on students), any tracking and changes will be documented clearly. Data on hard copies will not be erased and no white out will be used; any errors will be corrected by drawing a line through the error, printing the correction legibly above the value, and initialing the correction. All clerking will be done with a red pen. All clerked hard copies will be initialed and dated, and stamped "Clerked". Once clerked, all data will be double-entered to ensure validation of data entry.

Tracking of data collection will be carefully monitored, on a weekly basis, against the study timeline. Detailed tracking sheets of data collection and data management (clerking, entry and validation) will be maintained. All missing data points and surveys will be carefully tracked and documented. Data will be clerked for completion errors, missingness and skipping patterns. Missing data will be coded with a value of "-9". All items that are not applicable will be coded with a value of "88". We anticipate that there will be minimal missing data due to user entry error, given validation options in RedCap. For data entry into RedCap, validation will be set up so that entries cannot be made out of acceptable ranges.

The investigators will permit study-related monitoring, audits, and inspections by the IRB, the sponsor, government regulatory bodies, and University compliance and quality assurance groups, as applicable for this study, of all study related documents (e.g. source documents, regulatory documents, data collection instruments, study data). Participation as investigators in this study implies acceptance of potential inspection by government regulatory authorities and applicable University compliance and quality assurance offices.

13. Ethics/Protection of Human Subjects

13.1 Ethical Standard

The Investigators will ensure that this study is conducted in full conformity with Regulations for the Protection of Human Subjects of Research codified in 45 CFR Part 46.

13.2 Institutional Review Board

The informed consent forms, recruitment materials, and measures are submitted with this protocol to the IRB for review and approval. Approval of the protocol, recruitment materials and the consent forms will be obtained before any participant is enrolled. Any amendment to the protocol will be submitted for review and approval by the IRB before the changes are implemented to the study. All changes to the consent forms will be IRB approved.

13.3 Informed Consent Process

13.3.1 Consent/Assent and Other Informational Documents Provided to Participants

Consent forms describing in detail the purpose, procedures and risks of the study are given to the participant and written documentation of informed consent will be obtained prior to starting the study. The following consent materials are submitted with this protocol:

- Key Information Form: Parent
- Consent Form – Parent (Child participation and parent survey)
- Teacher Consent for Pre-K
- Teacher Consent for Kindergarten
- Child Verbal Assent Form
- Verbal Consent Script – Parent Survey

13.3.2 Consent Procedures and Documentation

Overview: Following various recruitment strategies (see Recruitment section above) across the 81 sites, parents will be invited to review the Key Information Form and the consent form. Pre-K parents will be invited to provide written consent to: 1) school-based assessments of their child and teacher ratings of their child, with no time demands for parents; 2) parent participation in surveys (two in Pre-K and one Kindergarten during the Spring/Summer), completed with the NYU study team in person or over the phone; 3) collection of NYC DOE administrative records of their child and 4) the use of information provided on the consent form for the study record; this information includes family/demographic information (child date of birth, language, child gender). Parents will provide consent to the release of records in the parent consent form. Additionally, parents will be asked to provide verbal consent to two additional surveys in Fall of Kindergarten and Spring/Summer of Grade 1.

Consent in Pre-K: Consent will be obtained from parents in written format when the students are in Pre-K. The consent forms will be provided in English and Spanish (see Parent Consent Form), given that the majority of families in the sites (>90%) speak English and Spanish, and that the intervention is provided in the schools in these two languages. As per NYC DOE procedures, consent forms provide parents with the option to consent to

the study (“yes, I give my consent to participate in this research study”), or to opt out of the study (select “no, I do not give my consent to participate in this research study”).

Written consent in Pre-K with parents will be obtained via any of the following methods:

- 1) The NYU study team will engage with parents on-site, including setting up a table for parents who choose to stop by during drop off/pick up, and speaking to parents attending Pre-K orientation or other school events. Pre-K parents will be invited to speak with study staff to learn more about the research study, and to provide consent if interested. The Key Information Form and the consent form will be reviewed in detail with parents. Study staff will be available to answer specific questions and obtain written consent from interested parents. Parents can also choose to review the information on their own time, and select to return the consent forms to the school at a later date. Parents can also visit the study link to access the materials electronically and consent electronically (see below).
- 2) School staff and the NYU study team will distribute the flyer, Key Information Form and consent form to parents via backpacks through the schools. Parents will be provided with contact card, which will include a key study contact name and contact information (phone number, email, and the study link to access the documents online). Parents will be invited to email or call study staff for more information. Parents can return the contact card and request for an NYU Langone staff member to contact them to learn more about the study. Study staff may call parents and answer questions, and/or email parents the Key Information Form and study link in RedCap (which includes the Key information form). Parents will be invited to review and return the consent form to the school, in a sealed envelope provided. The consent form will be placed in a sealed box, stored in a secure spot in the school, for study staff to retrieve.
- 3) Parents will be able to review the Key Information Form and consent form online, and provide e-consent, via RedCap. Parents will be provided with an online link and QR code on the contact card and flyer to access more information about the study. This link will direct parents to a secure study record in RedCap. Parents will review the Key Information Form and will be directed to select “NEXT” if they are interested in learning more, or “EXIT” if they do not want to proceed. When parents hit “NEXT”, they will be asked to provide their name and their email address, and to click that “yes” they are interested in getting more information. Parents will then be asked to go to their email. When they go to their email, they will click a link sent by RedCap. This is the verification process. Parents are able to verify their identity by going to their email and clicking the RedCap link provided in the email. This will immediately link them back to RedCap to review the consent form. Parents will have a chance to review the consent form electronically. They can then hit “NEXT” if interested in continuing, or “EXIT” to exit RedCap. By hitting “NEXT”, parents will be directed to provide consent. They will be asked to indicate whether they agree to participate or not participate. If they agree to participate, parents will be asked to click on “I consent to this study” button. They will then be asked to sign the consent form (by using their finger on a touch screen of a smart device, or with their mouse). As a final step, parents will be asked to verify their consent by clicking an “I agree to all of the above” verification. Once parents hit submit, parents will be immediately emailed a copy of the completed consent form with their typed verified name (and signature on the smart device) inserted in the consent form.

This will be the consent form for their records. Parents will be provided with a study contact name and number to call with any questions during this process.

At the time of consent in Pre-K, parents will also be asked to complete a short family information form, which provides information on the child's date of birth and gender, language (Parent Information Form – at consent).

Consent in Kindergarten and Grade 1: Parents will be asked to participate in two additional surveys over the phone with study staff: during Fall 2020 (Kindergarten) and Spring/Summer 2022 (Grade 1). Verbal consent will be obtained at each of these two time points for the survey. Verbal consent places less burden on parents to mail back paper versions or navigate the two-step process of e-consent. Recruitment in Pre-K indicated that parents did not have the technology, time or experience to complete e-consent in RedCap. Parents' familiarity with the study and participation in earlier phases of the study will make the verbal consent process more feasible and ensure that they are fully understanding all aspects of the study. Participation in the survey during these two time points also serves as a proxy and indication of consent by parents (in addition to the documentation of verbal consent).

For all options above, parents will be provided with a dedicated study contact person to contact should they have information about the study or the consent form. Since the NYU study team is conducting this study in collaboration with the NYC Department of Education, as part of the Thrive initiative, the leadership and teachers at each site are able to facilitate the distribution of consents and flyers, as per NYC DOE guidelines. NYC DOE staff (including the principals and teachers) will not actively recruit or consent families into the study. Only NYU Study staff will provide details on the study, answer questions about the study, and obtain consent (written, or by picking up the returned sealed consent forms).

Parents who agree to participate in the survey will be contacted by phone by study staff. The study staff will review the introductory script for the survey (see Parent Survey Introductory Script) prior to completing the interview (Times 1, 2 and 4). Following the second survey at the end of Pre-K (Summer 2020), all consented parents will be asked whether they are interested in participating in an additional survey in the Fall of Kindergarten. Similarly, at the end of Kindergarten (Spring/Summer 2021), parents will be asked whether they are interested in participating in one final survey at the end of Grade 1. Interested parents will be contacted in each time point and verbal consent will be obtained by study staff prior to completing the survey (see Verbal Consent Script – Parent Survey). Parents will be contacted at each time point, regardless of whether they completed the surveys at prior time points.

For **student assessments**, the study staff will review the instructions on the child assent form (see Child Verbal Assent Form). The study staff member will document the child's verbal assent to completing the assessment.

Pre-K teachers will be asked to complete surveys on students twice during the Pre-K year. Kindergarten teachers of students attending the 81 schools during Kindergarten will also

completed surveys on students once during the Kindergarten year. For this aspect of the study, teachers will only be reporting on students for whom consent is obtained for the child school-based assessments. As per the NYC DOE IRB guidelines, when teachers are asked to participate in research, whether to report on themselves or report on students, an informed consent form is required. Teachers provide consent that they are voluntarily completing surveys on the students (see Teacher Consent Form – Pre-K; Teacher Consent Form - Kindergarten). Teacher consent will be obtained by study staff prior to the distribution of the surveys that teachers will be asked to complete.

All tracking of consent information will be entered securely into RedCap. All identifying information (contact information, email, date of child's birth) will have additional restricted access in RedCap.

13.4 Participant and Data Confidentiality

All data will be entered into RedCap, which is HIPAA compliant and secure, with password protection, limited access to data by staff and different levels of access depending on the person's position on the research team. Data will be entered using only the unique study identification number. All final study files for analyses will be captured and finalized ensuring that no personal identifiable information (PII), including students', parents' or teachers' names, email addresses are included. Electronic data entered into RedCap that include contact identifying information (e.g., master list of consenting information, contact information/address, child's date of birth) will be securely saved, and will not be linked to the study data. There will be additional levels of protection and additional restricted access to this information.

Only the approved study staff will have access to the database and identifying information. Files with identifying information will be restricted to the Principal Investigators, Co-Investigators (limited access depending on scope), Data Analyst and Project Director at NYU School of Medicine. Linking of identifying study information to research data (which will be identified only with a unique study identification number) will be kept to a minimum. The identity of study participants will not be revealed in presentations or publications of study findings.

All participants will be assigned a unique study identification number. This identification number will be used to link each participant's assessment (students) and parent survey to measure change across time. School-based assessments with children will be captured electronically, on tablets, with identification numbers. Parent surveys will be completed with study staff in person or over the phone; responses to the surveys will be captured or entered electronically via RedCap. School-based assessments will not include any personal identifiable information (PII), including site name and participants' names, or capture IP addresses. Parents' contact information such as email address (for compensation) and additional contacts (for retention) will not be part of the study record, and only used for contact purposes. Teacher report on students will be captured on hard copy and entered securely into RedCap; no teacher or student names will be included on the survey.

Parent consent forms for child participation will include identifying information (name, child date of birth, child gender) and contact information (e.g., email). These consent forms will be stored in locked cabinets separately from other data (e.g., teacher report on students). Contact forms will not include information (such as a unique study identification number) that can link the participant to the electronic student assessments, teacher report on students or electronic parent surveys. For data collection purposes, a master list will be developed with the participants' (family) names and unique study identification number. The master file linking the contact information (i.e., name, email address) to the unique identification number will be stored securely with limited access to study staff, and stored separately from the study data, and will be used for the purposes of contacting parents for the follow-up surveys, and linking surveys over time. Date of birth will be converted to age and used to describe the sample and score the child-based assessments against age-normed guidelines. Only the Principal Investigators, Co-Investigators (based on scope on the study), Data Analyst and Project Director will have access to the master list and the identifying information.

Participants will be provided with an NYU phone number and NYU email address to contact study staff. Both the phone number and email addresses will be monitored and accessed by specific study staff (e.g., Project Director Linares Torres, Program Coordinator Colino, Research Coordinator Gelb). Parents will be invited to return a contact card if they want to learn more about the study. Parents will be provided with a link to access RedCap, where they will first see the Key Information Sheet, and will then review the consent form if interested in learning more.

14. Data Handling and Record Keeping

14.1 Data Collection and Management Responsibilities

All aspects of the evaluation procedures will be monitored and supervised by the Principal Investigators, Laurie Miller Brotman, PhD., Spring Dawson-McClure, PhD., and Andrea Troxel, ScD. Dr. Troxel will oversee the data monitoring, and analytical process and procedures.

Co-PI Spring Dawson-McClure, PhD will be responsible for all recruitment and consenting procedures. Dr. Dawson-McClure will serve as the direct supervisor of Program Coordinator, Cirielle Colino, who will oversee all recruitment and consenting activities. The daily logistics of the data collection will be coordinated by the Co-Investigators Demy Kamboukos, PhD, Alexandra Ursache, PhD and Gabriela Barajas-Gonzalez, PhD, and Project Director, Heliana Linares Torres, MS, all of whom have strong working relationships with the PIs. Dr. Barajas-Gonzalez will serve as the direct supervisor of Project Director, Heliana Linares Torres, MS, who will oversee all aspects of the study implementation, data collection and data management. Dr. Huang will directly supervise the Data Analyst, Sabrina Cheng, MPH on all data management and analytical approaches. Ms. Linares Torres will supervise the Research Coordinators, Gena Gelb, MS and Anya Urcuyo, and Ms. Cheng will supervise Research Coordinator Tiffany Huang, MPH.

Drs. Ursache and Kamboukos will be responsible for the child outcomes and Dr. Barajas-Gonzalez will be responsible for the parent outcomes. Dr. Ursache will be responsible for

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the aims related to neighborhood factors. Co-I Adhikari will be responsible for analyses, along with Dr. Huang.

Dr. Dawson-McClure will serve as the liaison with the NYC DOE on the procedures related to outreach, communications, and the administrative data. Dr. Kamboukos, with Ms. Sabrina Cheng, will be responsible for the partnership with the Research Alliance for NYC School for obtaining administrative data. Dr. Kamboukos, with Ms. Linares Torres, will be responsible for all submissions to the NYU Langone and NYC DOE IRBs.

All study staff is trained (and will be trained) in handling issues of identifying and reporting abuse or neglect and other dangerous situations. All staff will be trained on aspects of the study, including recruitment by Dr. Dawson-McClure and Cirielle Colino, and data collection by Dr. Kamboukos, Dr. Ursache and Ms. Linares Torres. All data entry storage and analysis will be closely performed and monitored by Dr. Troxel and Ms. Sabrina Cheng.

All personnel have completed the required training by the NYU School of Medicine IRB regarding research ethics and participant confidentiality.

14.2 Study Records Retention

Study documents will be retained for a minimum of 3 years after close out or 5 years after final reporting/publication. These documents will be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if applicable.

14.3 Protocol Deviations

The Principal Investigators will continuously monitor the study procedures and timelines (on a weekly basis). The Principal Investigators, led by Dr. Troxel, will identify and report deviations to the protocol, within 5 working days of the protocol deviation, or within 2 working days of the scheduled protocol-required activity. Protocol deviations will be reported to the NYU School of Medicine IRB, and the NYC Department of Education IRB, per their guidelines. The Principal Investigators will be responsible for knowing and adhering to the IRB guidelines.

14.4 Publication and Data Sharing Policy

This study is not funded by the NIH and there are no data sharing policies or requirements by the funder. However, the investigators will ensure that the public has access to the published results of this research, and follow guidelines similar to the NIH Public Access Policy.

15. Study Finances

15.1 Funding Source

The evaluation for this study is funded by the Einhorn Family Charitable Foundation, Bezos Family Foundation and Overdeck Family Foundation, grants to PI, Laurie Brotman, PhD.

15.2 Costs to the Participant

There is no cost to participants to be part of this study.

15.3 Participant Reimbursements

Participation in the study is completely voluntary. Participants do not have to complete the entire study to be eligible to receive compensation. All Pre-K students whose parents return the consent form (whether parents consent for their child to participate or not), will receive a book for their participation. Parents will be sent a \$25 gift card after the completion of each parent survey. This is up to a total of \$125 in gift cards or a Visa/Mastercard during the course of the study, if they participate in all five surveys. [Note that parents who are not eligible for participation, but express interest in completing a survey for programmatic reasons, will be compensated \$50, which is the same amount eligible parents receive in Pre-K).

As per NYC Department of Education policies, teachers cannot be directly compensated for participation in research. As an alternative, it is recommended that teachers receive donations for their classrooms. Teachers will receive donations via AdoptAClassroom.org, which is a nonprofit organization created to help teachers obtain supplies for their classrooms. Incentives will be provided directly to the teacher, using the school email, who can then use the funds to shop online for supplies delivered to the school. Pre-K teachers will receive a donation for \$50 for the completion of surveys on students in the Fall and an additional donation of \$50 for completion of surveys on students in the Spring of Pre-K. Kindergarten teachers from the 81 schools will receive a donation of \$50 for the completion of surveys on students.

As an appreciation for the sites' time related to the study, participating sites will receive a donation of materials to promote social emotional learning and support school activities. All sites will receive a donation of materials, valued at \$300, in Fall 2019 and Fall 2020 (when the students are in Kindergarten). Sites will receive the donation of materials, regardless of their level of family consent and teachers' participation in completing surveys.

16. Study Administration

16.1 Study Leadership

The study leadership includes the three Principal Investigators: Laurie Brotman, PhD, Spring Dawson-McClure, PhD, and Andrea Troxel, ScD. It also includes the Co-Investigators, Vanessa Rodriguez, EdD, Demy Kamboukos, PhD, Keng-Yen Huang, PhD, R. Gabriela Barajas-Gonzalez, PhD, Alexandra Ursache, PhD and Sam Adhikari, PhD.

17. Conflict of Interest Policy

There is no conflict of interest.

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19. Attachments

- Key Information Form – Parent
- Consent Form - Parent (Child and Parent Participation)
- Teacher Consent Form – Pre-K
- Teacher Consent Form – Kindergarten
- Child Verbal Assent Form
- Verbal Consent Script – Parent Survey

- Introductory Script – Parent Survey
- Instructions for Teacher Report on Students
- Measures –School-Based Assessment with Students (Appendix A), Teacher Report on Students (Appendix B), Parent Survey (Appendix C)
- Family Information Form (at consent)

- Schedule of Events (Appendix D)

- Family Recruitment Poster (2 versions: Coming Soon, Join Us)
- Family Recruitment - NYU Study Staff Contact Information Card
- Family Recruitment - Flyer
- Principal/Site Recruitment – Principal Email
- Principal/Site Recruitment - FAQ
- Principal Letter/Approval Signature Form

Appendix A: School-based Assessments with Students

Informant	Domain	Measure		Spring 2020 Pre-K	Spring 2021 K
Child	Language	Activity: <ul style="list-style-type: none"> Receptive One-Word Picture Vocabulary Test (ROWPVT) – 4th edition 		✓	✓
Child	Social Emotional Learning (Self-Regulation - Executive Function)	Activity: <ul style="list-style-type: none"> Hearts and Flowers Dimensional Change Card Sort (DCCS) Pencil Tap 		✓	✓
				✓	✓
				✓	✓
Assessor		Observation: <ul style="list-style-type: none"> Preschool Self-Regulation Assessment (PSRA) 		✓	✓
Child	Social Emotional Learning (Emotional)	Activity: <ul style="list-style-type: none"> Assessment of Children's Emotional Skills (ACES) Emotion Recognition Questionnaire (ERQ). Dot Probe 		✓	✓
				✓	✓
				✓	✓
Child	Body Size	Direct Assessment <ul style="list-style-type: none"> Body Mass Index (BMI) 		✓	

Parent Report and Teacher Report on child outcomes are on Appendices B and C.

Appendix B: Teacher Report on Students

<u>Informant</u>	<u>Domain</u>	<u>Measure</u>	Fall 2019 Pre-K	Spring 2020 Pre-K	Spring 2021 K
Teacher	Child Feelings, Behavior and School Functioning	<ul style="list-style-type: none"> • Child Sleepiness • Children's Behavior Questionnaire 	✓	✓	✓
		<ul style="list-style-type: none"> • Social Competence Scale 	✓	✓	✓
		<ul style="list-style-type: none"> • Student-Teacher Relationship 	✓	✓	✓
		<ul style="list-style-type: none"> • School-Readiness Questionnaire 	✓	✓	✓

Appendix C: Parent Survey

Informant	Domain	<u>Measure</u>	Fall 2019 Pre-K	Spring/ Summer 2020 Pre-K	Fall 2020 K	Spring/ Summer 2021 K	Spring / Summer 2022 G1
Parent	Parenting	<u>Survey:</u> <ul style="list-style-type: none"> • Parenting Practice Scale • Mindfulness in Parenting Questionnaire/Interpersonal Mindfulness in Parenting • Parental Engagement of Families Questionnaire • Child Routine Inventory • Evidence-based Strategies • Family and Provider/Teacher Relationship Quality 	✓	✓	✓	✓	✓
Parent	Parent Well-Being	<u>Survey:</u> <ul style="list-style-type: none"> • PHQ Scale • Short Depression Scale (CESD) • Financial Stress • Parenting Strain • Hope Scale • Multidimensional Scale of Perceived Social Support • PROMIS 10 • PROMIS 4 	✓	✓	✓	✓	✓
Parent	Child Feelings and Behavior	<u>Survey:</u> <ul style="list-style-type: none"> • NIH Toolbox Item Bank • Social Competence Scale - Parent Version • Pediatric Symptom Checklist • Child Health 	✓	✓	✓	✓	✓

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Parent Context	<u>Survey:</u> <ul style="list-style-type: none"> • Perceptions of Neighborhood Safety • Discrimination Fear • Demographics* 	✓	✓	✓	✓	✓
	<ul style="list-style-type: none"> • <u>Coronavirus Impact Scale</u> • <u>US Household food Security Survey Module: Six-Item Short Form</u> • <u>Community Cohesion</u> 		✓	✓	✓	✓

*Some demographic items are asked only in Time

Appendix D

Schedule of Events

Activity	Fall 2019 Pre-K	Spring 2020 Pre-K	Fall 2020 K	Spring/ Summer 2021 K	Spring/ Summer 2022 G1	Spring 2023- 2026 G2-G5
Study team procedures						
Recruitment	X					
Informed Consent	X					
Verbal Consent – Parent Survey			X		X	
Data Collection						
School-based assessment with students		X		X		
Teacher Report on Students	X	X		X		
Parent Survey	X	X	X	X	X	
Administrative Data						
NYC DOE data (student level)		X		X	X	X
Analyses						
Data Management	X	X	X	X	X	X
Data Analyses		X	X	X	X	X