Patient Centered Enhancements in School Behavioral Health: A Randomized Trial

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PCORI RESEARCH PLAN TEMPLATE

RESEARCH STRATEGY

A. Specific Aims. Will test the incremental impacts of evidence-based Partnership enhancements to a framework for evidence-based practice (EBP) in school behavioral health (SBH) termed Clinical Services Supports in a four-year intervention for students in middle school.

- Aim 1: Evaluate the impact of the Partnership intervention in increasing the number of students and families receiving services and expressing satisfaction with them.
- Aim 2: Evaluate the impact of the Partnership intervention on students' social, emotional/behavioral (EB) and academic outcomes.

The original research plan included a third study aim: Evaluate the follow-up effects of the intervention on social, EB, academic and health outcomes in a sample of students followed into high school. This aim was removed in a subsequent revision of the research plan (May 2023) due to significant challenges in contacting students who have been transferred to a new therapist in high school or who have been discharged from services. Additional references to Aim 3 have been removed from this plan to reduce confusion, but will be preserved in the appendix.

B. Background. There is an alarming gap between the EB needs of youth and available services, with up to one third of youth needing mental health intervention (1-3) but less than one third receiving any services, with more significant gaps for cultural/ethnic minorities and other underrepresented groups (4). When EB problems in children and youth go undetected and/or untreated, they tend to cause functional impairment that persists over time (5,6) contributing to problems including school failure, dropout, underemployment, involvement in the criminal justice system, and early death (7-10). Middle school is a particularly important time in child and adolescent development (11,12), with more serious EB problems often emerging during this time period (13,14), and offering an important window to provide effective services to youth to help to assure a positive life trajectory through K-12 education and beyond (15,16). School behavioral health (SBH) programs, involving school-community-mental health partnerships increase access to needed mental health services for all students, and for minority youth (16). Increasingly, education and mental health systems are collaborating to provide effective programs within a multi-tiered system of support (MTSS) involving promotion and prevention for all students at Tier 1; early intervention for students showing beginning problems or with elevated risk at Tier 2, and treatment services for students presenting more intensive EB problems at Tier 3 (17).

For over a decade, the Principal Investigator (PI), Weist, and Co-Investigator (Co-I) and MD site PI, Hoover have been involved in a range of research, practice and policy efforts to improve the depth, quality and impact of Tier 1, 2, and 3 services within the MTSS (17) and have led two consecutive randomized controlled trials (RCTs; 2003-07; 2010-15) funded by the National Institute of Mental Health to test a Clinical Services Support (CSS) framework for enhancing evidence-based practice (EBP) in SBH, with this being the core intervention to be implemented in middle schools involved in this study, termed the Wellness Group. The CSS framework packages together EBPs of family engagement, modular evidence-based practice, quality assurance, and implementation support. The first trial showed improvements in quality services and EBP (18), and the second trial replicated these findings and also documented increased numbers of students/families receiving effective services (19). Through a recently completed PCORI engagement award, intensive qualitative analysis with families, clinicians and diverse stakeholders documented two additional critical theme areas to further improve SBH services – enhancing mental health literacy and stigma reduction, and improving family-school-mental health partnerships. Of more than 18 specific recommendations of stakeholders, these were the two top-rated services enhancements, with stakeholders emphasizing that these enhancements will increase the likelihood that students in need will receive services (through mental education/stigma reduction) and that these services will be more acceptable and effective (throraugh enhanced partnerships with families/students). Families and youth may not use mental health or SBH services related to poor knowledge of them, stigma, and perceptions of unequal, and even condescending relationships with education and mental health system professionals. This study addresses a critical gap

in evidence on the influence of these two partnership enhancements as factors that we hypothesize will enhance effectiveness and impact of the evidence-based strategies included in the Wellness intervention. The intervention condition, or Partnership Group, will consist of these two stakeholder enhancements in addition to the CSS framework. As such, we believe this study will support improved decision making and resource allocation by education and mental health systems in placing greater priority on evidence-based SBH and predicted amplifying factors (the two stakeholder enhancements (SE)). The primary decisional dilemma addressed is *should significant efforts be made to enhance knowledge and reduce stigma, and improve collaborative approaches to amplify the impacts of evidence-based SBH, or are these efforts not necessary*?

The study will test the contribution of these two SE's in improving the productivity of clinicians and positive impact of SBH services. The study involves 22 middle schools, with 10 in Maryland (MD) and 12 in South Carolina (SC), with all 22 schools receiving the Wellness intervention, and half of them (5 in MD and 6 in SC) randomly assigned to the Partnership condition, with impacts explored through a longitudinal randomized controlled trial (RCT) operating for three years in grades 6-8. We hypothesize that the Partnership enhancements will help to foster a more supportive culture for SBH, and increase the impact of evidence-based services toward significantly improved social, EB, and academic outcomes for participating students, and provide a critical precedent for prioritizing patient and stakeholder involvement and active guidance in SBH, an increasingly prominent field.

C. Significance. The proposed study is positioned to offer essential guidance to collaborative partnerships involving schools, families and youth, mental health and other youth serving systems to maximize effective decision making on the ongoing improvement of SBH programs toward enhanced social, EB, and academic outcomes. To enhance SBH with significant and meaningful input from diverse stakeholders, the PI and colleagues have been interacting with stakeholders including youth and families receiving services for EB problems, clinicians, researchers and diverse youth-serving system staff and leaders to obtain guidance on the most important enhancements to these services. Beginning in 2015, forums were held with these stakeholders and five initial critical themes were identified (on partnerships, school-wide approaches, quality, effective implementation, and cultural competence). The PI and team were fortunate to receive a PCORI Eugene Washington Engagement award in late 2015 enabling research forums with diverse stakeholders held throughout SC in 2016 on each of these five themes, and formal qualitative analyses of them. From analysis of transcripts of these research forums, two overarching themes representing critically important enhancements to SBH services were identified by patients and stakeholders: 1) Broadly train all school stakeholders in mental health and purposefully reduce the stigma involved in seeking SBH services, and 2) increase partnerships among youth, families, schools and mental health clinicians. For both of these critical enhancements the research team has carefully identified evidence-based interventions that will augment the existing evidence-based CSS framework for SBH. While each of the Wellness intervention components is evidence-based and commonly implemented (16), the impact of services has been limited by underutilization of services related to poor knowledge of mental health and stigma (20,21), and constrained quality of services related to limited partnerships among patients, families, and providers (20,22). We hypothesize that findings from this study will have significant impacts on practice and policy in the SBH field through inclusion of the Partnership enhancements that address these limiting factors and enable increased productivity and impact of services.

This application is highly responsive to PCORI's call for comparative effectiveness research that explores alternative features of healthcare systems. While the SBH field has developed considerably in recent years (16-18), efforts to significantly involve patients and diverse stakeholders in improving the depth, quality and impact of services have been severely lacking (20). This will be the first study to test SBH enhanced by critical recommendations from families, educators, clinicians and other stakeholders that we predict will be associated with new levels of productivity and impact. To obtain stakeholder guidance on the Partnership intervention, a survey was given to attendees of the 2018 Southeastern School Behavioral Health Conference. The survey asked participants to rate 10 service components, 4 Wellness and 2 Partnership and 4 alternative components (e.g., "helping students have insight into their problems"). Ninety-two attendees from a wide variety of disciplines and backgrounds, including school administrators, educators,

school counselors, school-based clinicians, psychologists and research staff, and community and family organizations (including patients and parents), and school resource officers, responded. The six Wellness and Partnership components (Mean = 5.7; α = 0.89) were on average rated as significantly more important than the four comparison components (Mean = 5.3; α = 0.79): t (92) = 96.29, $p < .01$. The minimum, maximum, mean, and standard deviation (SD) for each component's ratings are presented in Tables 1 and 2 in the Appendix.

D. Study Design/Approach. The study will involve 22 middle schools (12 in SC, 10 in MD) in a cluster-RCT, with all schools receiving the Wellness intervention and half of the schools (6 in SC, 5 in MD) randomized to receive enhanced intervention including the two SEs (Partnership). Stratified random assignment of schools to the Wellness Group or the Partnership Group will be conducted. We will then use validated procedures (23, 24) to further stratify schools within each state. We will construct a composite inflate-suppress score derived from school data on rurality, average number of students per grade, percent white, percent receiving free/assisted lunch, and average school test performance. Rurality within the two study sites will be operationalized by using a federally developed classification system used by The US Census Bureau (i.e., a 9-point, "Rural-Urban Continuum"). The coding scheme will distinguish three metro county categories based on population size, and six non-metro county categories based on degree of urbanization, as well as adjacency to other areas and metro proximity. Per operationalization of rurality in the federally-based coding continuum, we can confirm that the SC study sites contain county classifications of rural and suburban, while the MD site is exclusively urban. We will separate this composite into three strata and randomly assign schools from these strata to receive either the Wellness Group or the Partnership Group.

In the 5-year longitudinal design, Year 1 will involve administrative start up, collection of pre-assessments and intervention launch; Years 1-4 will involve intervention versus comparison while participants are in 6th through 8th grades. Year 5 will involve analyses and dissemination. A comprehensive implementation manual will guide the study and will be updated and improved regularly through active guidance of a Stakeholder Advisory Board (SAB, see Tables 3 and 4 in Appendix). The SAB will provide significant input as this manual is developed during the study start-up period from January through July, 2019, and progressively improved through study duration (see Gantt chart in Figure 1 of the Appendix for a review of all study activities in time).

Conceptual Framework. We predict the Partnership intervention will improve school culture so that staff and students are more knowledgeable about mental health, less concerned about stigma, and more proactive in identifying students in need and connecting them to more intensive Tier 2 or Tier 3 services; more students/families receive Tier 2 and 3 services and receive them in a more timely manner; students and families are more invested in services, empowered to influence treatment directions, experience greater therapeutic alliance with SBH staff, and receive a higher dose of evidence-based services; and, impacts of evidence-based services are amplified based on greater knowledge of mental health. These factors will be associated with better performance on measures of social, EB, and academic functioning than students in the Wellness Group alone.

Engagement Plan. The engagement plan has been informed by lessons learned from the recent PCORI Eugene Washington Engagement award, and reviewer feedback from the prior application. The SAB has actively guided our work and this resubmission, with some members providing input since 2015, and new members (i.e., educators, additional family members, payers) added based on PCORI guidance. The SAB has 13 members in SC and 10 in MD (23 total) and includes: patients/caregivers (some of whom are end users at study schools), educators, mental health/community partners, public and private funders, and community partners (see Tables 3 and 4 in Appendix for a full listing of members by site). Please note that the SAB is representative of study sites in relation to racial/ethnic/cultural background of students. The SAB will collaborate at multiple levels, as a full 23-member board, within SC and MD, and in three subgroups of patients/caregivers, educators, and mental health/community partners. The SAB subgroups will convene in bi-monthly conference calls for one hour to provide input and feedback in all three domains of the PCORI engagement rubric: Planning, Conduct and Dissemination. Each SAB member will be compensated $50 per hour for their time spent on the calls, as well as the time they spend reviewing materials offline (estimated at 6 hours annually). Additionally, the SAB will meet in person once annually, to engage in more comprehensive discussion of

the study, with travel stipends planned for all travel expenses incurred to assure that travel is feasible for all members. In years 1, 3 and 5 the full 23-member board will convene in person, in years 2 and 4, the SC and MD SAB members will convene in separate locations but with opportunities for virtual audiovisual interaction. During year 2, the SC and MD SAB meetings will be held via Zoom video conference in lieu of an in-person meeting due to COVID-19. The initial SAB meeting, focusing on introductions and planning the study (including dissemination), will be held in April, 2019, in advance of the 6th annual meeting of the Southeastern School Behavioral Health Community (SSBHC), which was established through the PCORI Engagement Award (see www.schoolbehavioralhealth.org). The final SAB meeting, focused on dissemination and scaling up of the Partnership intervention will be held in March 2023, at the 10th annual Southeastern School Behavioral Health conference, started by the PI and colleagues in 2014. The SAB will be co-directed by Dr. Robert Stevens, who has significant experience with PCORI research and Dr. Reverend Al Hathaway, a pastor at Union Baptist Church in Baltimore, and a national leader in faith-community collaboration to improve human services. Patient engagement will be led by June Greenlaw who is both a parent partner as well as the engagement specialist on the previous engagement award. Greenlaw will be the point person for all SAB members and subgroup leads and will communicate with them frequently during the proposed study time period.

Engagement in Planning the Study. As reviewed above, associated with our prior PCORI engagement award, the SAB has been in place since 2015 and has guided our work up to the present, including eight research forums on five priority themes (partnerships, school-wide approaches, quality, implementation, cultural competence) and three priority populations (youth in child welfare and juvenile justice, and from military families). Systematic qualitative analysis of all focus groups confirmed these prioritized themes and the two with the highest frequency represent the two components in the Partnership intervention. For both enhancements we have identified evidence-based strategies for implementation. The SAB has recently been expanded for this proposal, and has endorsed our study plan and choice of comparators, the evidence-based Wellness intervention for 11 comparison schools (6 in SC, 5 in MD), and the Partnership intervention for 11 target schools (6 in SC, 5 in MD). The SAB has also provided critical guidance to enhancing our engagement and dissemination plans, as well as plans for effectively reaching underserved and minority populations.

Engagement in Conducting the Study. During project start up, the SAB will identify an informal project name and logo that will be used on study materials, a website, ways to most effectively communicate with patients, families and stakeholders and ways for them to access information and materials from the study. The SAB will review parent/guardian recruitment letters and provide input to assure understandability and sensitivity of the language used, and will improve overview materials that will be used when orienting school and mental health staff to study procedures/resources. Throughout implementation, the SAB will be provided with frequent progress updates including information on successes and challenges encountered related to recruitment, implementation of both interventions and data collection. The SAB will review preliminary (aggregated) data reports and assist in interpreting them to adjust the research strategy as needed. In addition, data will be disaggregated for analysis of service receipt and impacts for groups varying on grade level, age, gender, race/ethnicity, and special education status. If disparities in service receipt or outcomes are identified, the SAB will guide the study team in making adjustments to assure responsiveness in services. The SAB will also identify additional research questions to be pursued and will be encouraged to participate actively in supplementary studies. Additionally, during in-person meetings, we will seek feedback from the SAB on their level of engagement in the study and ways to improve engagement.

For the Partnership condition, two family advocates serving on the SAB (1 in MD and 1 in SC) will co-lead training for clinicians, school staff and selected parent leaders from each of the 11 schools at the beginning of each year, with emphasis on family partnerships and cultural humility. Parent leaders will be carefully selected, assuring they are racially representative of their school to mitigate barriers of mistrust from underserved and minority populations. Parent leaders will be compensated for the time spent to collaborate with fellow parents and school staff to communicate about and promote the study, as well as perform outreach to minority populations to increase their access to effective SBH services, as well as other programs and services available in the school and community.

Engagement in Quality Improvement and Dissemination. The Extension for Community Healthcare Outcomes (ECHO) model (25, 26) will be used to create hub and spoke learning networks between the research team and SAB (hub), and 11schools implementing the Partnership intervention (spokes). Project Manager, Brooke Chehoski, along with an additional research specialist (Samantha Reaves) and two Project Family Leaders (Jenah Cason and Susan Tager) will attend ECHO training at the University of New Mexico. Guided by the SAB and research team, an ECHO hub team will develop training materials and coordinate case studies for the 10 Partnership schools, with each school including the clinician, parent leader, school-employed mental health staff (e.g., counselor, psychologist, social worker) and educators. The ZOOM platform (www.zoom.us) will be used to facilitate ECHO clinics, which will be scheduled three ECHO clinics throughout the school year. These will occur for Partnership schools for the four years of intervention vs. comparison (2019-2020, 2020-2021, 2021-2022, and 2022-2023 school years) and participant attendance will be tracked as a fidelity measure, with outreach to individuals as indicated. In addition, use of the ECHO model will help to provide SBH consumers and providers with rapid information on which interventions work best for particular challenges in a variety of subgroup populations. In the academic year following intervention vs. comparison (2024-2025) the ECHO program will be expanded to the 11 comparison schools to promote generalization of the study innovation. Beginning in January of 2024, the ECHO program will be used with key stakeholder groups in SC, MD and nationally (e.g., family advocates, school psychologists, counselors, educators, physicians) to assist in dissemination. Dr. Eve Fields, a board-certified psychiatrist with significant experience working with adolescents and a leader in using the ECHO model for improving psychiatry services in SC, will guide our use of the ECHO model.

The SAB will assist researchers with refining a preliminary dissemination plan during the in person meeting in Year 1 to assure that all study activities are conducted in a way that maximizes the potential for disseminating findings to SBH consumers and providers, with parent leaders having a significant role in assuring access to this information by diverse end users. In Year 5 of the study, SAB efforts will focus on interpreting findings and synthesizing the knowledge gained in both traditional ways (academic journals, conference presentations) as well as creative methods that may be more accessible for patients and stakeholders such as Infographics to be rapidly distributed in a variety of settings to a large audience. All presentations and publications will be identified and prepared using SAB guidance. Through resources of large regional/national networks led by PI Weist (SSBHC, www.schoolbehavioralhealth.org) and Co-I/MD site-PI Hoover (CSMH, http://csmh.umaryland.edu) we estimate a reach of study findings and lessons learned (all guided by patients and stakeholders) to more than 100,000 leaders and stakeholders.

Comparators. At each of the two sites, SC and MD, there will be 5 schools/clinicians randomly assigned to the Wellness Group, and 6 schools/clinicians randomly assigned to the Partnership Group for 22 total participating middle schools. The grant will support one day per week of clinician time in all study schools. In addition, at each site there will be two supervisors/senior trainers, one for Wellness, and one for Partnership. Supervisory assignments will be kept separate for each condition, all training events/meetings for the two groups will be held separately and all participants will be asked to not share information with the other group.

1. Clinical Services Support (Wellness) Intervention. The Wellness intervention involves four components: 1) Systematic Quality Assessment and Improvement using The SHAPE System (see below), developed by the Co-I/MD site-PI Hoover and colleagues at the CSMH, 2) a family engagement intervention emphasizing clinicians working with families in a collaborative fashion, 3) modular evidence-based practice, involving targeting the most important cognitive-behavioral skills to address common problems of anxiety, depression, trauma, and conduct problems, and 4) implementation support, involving SBH clinicians meeting twice per month for 60-90-minute training sessions for these above components. The evidence base for each of these four components is strong (20, 27-32), with the Clinical Services Support representing an integration of them into a package, associated in two prior studies with higher levels of each of the four components, and enhanced clinical productivity and service receipt by students/families (18, 19). More detail on the Wellness intervention and its four components is provided here: Quality Assessment and Improvement. The School Health Assessment and Performance Evaluation (SHAPE) System (see www.theshapesystem.com) is a federally funded, public-access, web-based platform to support quality improvement in SBH. Using this system, school

teams are able to self-assess their progress in various domains of quality services using the *SBH Quality Assessment Tool* (SBHQAT; 29, 30) which includes seven domains and 62 items. Mean scores for items within each domain are classified as "emerging," "progressing," or "mastery" providing guidance to schools and districts on quality improvement strategies. Family Engagement. The family engagement intervention is based on research focused on improving retention of children and families in community mental health services (32). The program is based on Theories of Reasoned Action, and Planned Behavior (33), and includes emphases on problem identification, engagement skills, service delivery options, and treatment management skills. Modular Evidence-Based Practice. To overcome many challenges associated with implementing treatment manuals (34,35), modular approaches (27,36) that provide clinicians with competency training in core practice elements for particular disorders are increasingly being utilized and showing superior impacts on provider preference and on student outcomes (37-39). As used in the prior NIH-funded RCTs (18,19), the PracticeWise system (40) will be used by clinicians to guide their selection and implementation of evidence-based cognitive behavioral therapy skills to address the most common child and adolescent disorders of anxiety, depression, conduct problems, and trauma related problems. Implementation Support. An extensive literature has documented the importance of attending to the implementation of evidence-based practices to attain desired intervention outcomes (28,38,39). Based on this literature and guidance from the National Implementation Research Network, implementation support will include ongoing training in the three elements of quality improvement, family engagement, and modular evidence-based practice in twice monthly, 60-90-minute sessions led by two senior trainers, with one assigned to work with the Wellness Group and the other assigned to work with the Partnership Group. During the spring 2020 semester, due to the impact of COVID-19, the Partnership teams in MD and SC began meeting together using Zoom technology. This decision was made quickly following decisions in both states to close public schools and to require non-essential employees to work from home. Given the early success of this model and in alignment with the teleECHO framework, the Partnership teams will continue to meet together for the duration of the study. In addition to streamlining preparation time and effort by senior trainers, this shift will align training content and delivery across sites. One meeting per month will be facilitated using the teleECHO format, which includes one or more case presentations by a clinician and a separate didactic instruction on study elements, facilitated by a content expert. Per prior studies (18,19), the implementation support component will follow a Plan-Do-Study-Act framework (41). The senior trainer will prioritize a strong relationship with all clinicians, addressing problems constructively and matching training to clinician learning styles (28,42).

2. Stakeholder Enhancements (Partnership) Intervention. The Partnership intervention will involve all of the above components of the Wellness intervention, and the two additional components identified by patients and stakeholders from the recent PCORI award and from relevant research literature. The Wellness intervention will focus on these two evidence-based enhancements working together in a school-wide strategy focused on clinicians working actively on school teams and assisting in promotion/prevention -Tier 1, early intervention - Tier 2, and treatment -Tier 3 within the multi-tiered system of support (MTSS). Clinicians will actively participate in the MTSS to help improve school culture, and enable effective implementation of all intervention elements including SEs. In each of the 11 Partnership schools, a parent leader, and school-employed mental health professional (e.g., school psychologist, counselor) will be assigned to work with the clinician and implementation team, one day per week through resources allocated from the grant. The two SEs will be: Mental Health Literacy and Stigma Reduction. To enhance mental health literacy and focus purposefully on reducing the stigma of seeking SBH services, a program called The Guide, developed in Canada and beginning to be used in the US and other nations, will be used (see www.teenmentalhealth.org/curriculum). The Guide is a teacher-delivered mental health curriculum for middle and high schools. Teachers, as supported by clinicians and parent leaders will deliver the program, which includes didactics, interactive classroom activities, and experiential learning. The Guide consists of modules focused on stigma and reducing it, understanding mental health, mental health challenges, and seeking help/finding support, with positive outcomes of increased mental health knowledge and reduced stigma for participating students (43,44). The program is being used throughout Canada, in Washington State, and in a number of other countries, and it has strong feasibility and acceptability data, helping to support its growth and sustainability in

Canada and other nations (43, 44). For each of the 11 Partnership schools (5 in MD, 6 in SC) in the summer of the three intervention vs. comparison years, developers of The Guide Drs. Stan Kutcher or Yifeng Wei will conduct a one-day training involving the SBH clinicians and senior trainers (1 from SC and 1 from MD), as well as with three teacher leaders recruited from each of the schools, with one each from 6th, 7th, and 8th grade. For individuals who cannot attend the summer training, the research team will host a compensatory training utilizing video segments recorded during the summer training. Following one-day training, coaching calls and webinars will be conducted with this group by Kutcher or Wei (alternating involvement with each site). The SBH clinicians and these teachers will be active on the schools' MTSS teams, and will in turn provide training on The Guide to these teams, and clinicians will use materials in sessions with students and families. In each school, this group will also use grade-level meetings, MTSS meetings, and other avenues to disseminate information on The Guide to other teachers, and will encourage teachers to sign up and go through a free on-line course on it. The online self-study course takes between 4 to 6 hours to complete, and is associated with continuing education units and teacher education certificates from the University of British Columbia (http://educ.ubc.ca/), which we believe will be an important incentive (e.g., facilitating promotion opportunities). Teachers and clinicians involved in implementing The Guide program will complete The Guide Curriculum Assessment, a measure with adequate psychometric properties (43,44) at the beginning and end of each school year. Students receiving Tier 3 intervention will also complete this measure (student version) at intake and every three months, integrated into the Tier 3 measurement strategy (see below). As result of the COVID-19 crisis in late spring of 2020, schools began implementing distance learning for all students. Because of this shift, teachers were temporarily unable to facilitate The Guide curriculum in classrooms as planned. One Maryland school teacher and clinician have continued to facilitate a live, interactive session using the Blackboard platform, in addition to one South Carolina teacher who is using the Google platform. These two schools are able to maintain essential components of the material as articulated by consultants Yifeng Wei and Andrew Baxter, and seek additional guidance from the study team and consultants as needed. For schools that are unable to facilitate virtual delivery of The Guide curriculum, clinicians will facilitate regular meetings with teachers at their respective schools. These meetings are intended to achieve two goals: 1) review The Guide content to increase knowledge and confidence and 2) create an implementation plan for delivering The Guide in classrooms when schools resume in-person instruction. The study team will track all of these activities via monthly reports submitted by clinicians and teachers, including whether sessions were held virtually or in person. With IRB approval from all sites, class rosters including school-issued student identification numbers will be collected by the study team. This strategy will serve as an additional enrollment strategy, as the team will be able to include variables related to classroom participation with The Guide in later analyses of student data (e.g., grades, attendance, discipline referrals) to assess any changes that may be associated with the curriculum. All decisions related to The Guide curriculum are made through collaboration with Yifeng Wei and associates at teenmentalhealth.org. In addition, Wei will serve as a content expert on ECHO calls with teachers and clinicians during years 2 and 3 of the study.

Enhancing Family-School-Mental Health Partnerships. The Partners for Change Outcome Management System (PCOMS) has been used for more than two decades to enhance patient involvement in mental health services and to improve the therapeutic alliance between patients and clinicians (see 45-47). Foundational to the program are two brief measures: The Outcome Rating Scale (ORS, 46) and the Session Rating Scale 3.0 (SRS, 47). The ORS measures progress in EB symptoms and social relationships (completed at the beginning of the session) and the SRS measures therapeutic alliance including quality of the relational bond, and agreement on treatment goals and methods (completed at the end of the session). Both scales take less than a minute to complete and score and are available for free online at www.talkingcure.com. The PCOMS program helps to promote dialogue on how therapy is proceeding, increases chances for active student/parent input, and helps to assure that both groups are in sync with treatment plans and progress. In addition to the PCOMS system, SBH efforts in Partnership schools will be enhanced by active participation of the parents on MTSS teams, which will also receive regular guidance, ideas and resources from the study's SAB (see Engagement Plan). Please note that family-school-mental health partnerships will also be enhanced by ongoing involvement and guidance by the family advocate at each site, and parent leader at each of the 11 Partnership schools.

In addition, in each of the 11 Partnership schools, clinicians and MTSS teams will conduct trainings on both Partnership Group enhancements, as appropriate. Clinicians and MTSS teams should leverage grade-level meetings to provide trainings and information as appropriate for each school environment.

To help to assure the cultural responsiveness of the Partnership intervention, family advocates and parent leaders will provide training and ongoing support to SBH clinicians and MTSS teams to: 1) Consider the family's cultural preferences when prioritizing family needs, 2) address culturally specific sources of mental health stigma, and 3) to identify obstacles to involvement in services that are unique or particularly relevant to racial/ethnic minority families and to develop strategies to overcome these obstacles. Further, Dr. Colleen Halliday-Boykins of the Medical University of South Carolina, who possesses expertise in racial/ethnic discrimination and bias in youth as well as racial/ethnic disparities in problem behavior, will provide training to clinicians and schools. She will provide on-site unconscious racial/ethnic bias trainings to members of school teams in year 1, with additional support via phone and video conferencing during additional years. Similar to The Guide training, a compensatory training will be held for individuals who are unable to attend the summer training.

*Assuring and Monitoring Intervention Fidelity***.** In addition to the implementation manual including general and specific guidance for all intervention elements, we will monitor intervention implementation to assess fidelity along three domains: Adherence, Exposure/Dosage, and Participant Engagement. Based on procedures established for the prior RCTs funded by NIH (18,19), fidelity of the Wellness intervention will be assessed by a monthly self-report completed by SBH clinicians with self-rated performance on all four dimensions. For clinicians in the Partnership condition, with guidance by SAB, items will be added to reflect critical components of both Partnership enhancements. Clinical productivity of clinicians in service types of assessment and intervention will also be monitored (see below). For the Tier 3 measurement plan (see below), participant engagement will be assessed every three months with the Parent Participation Engagement Measure (48), completed by students and parents. The research team will collect and analyze fidelity process forms promptly with information going to the SAB for analysis and recommendations back to the research team. Intervention feasibility and acceptability will be measured using the Usage Rating Profile – Intervention Revised (49), a measure of those factors believed to influence treatment usage at the individual (i.e. Acceptability, Understanding), intervention (i.e., Feasibility), and environmental (i.e., Family-School Collaboration, System Climate, System Support) levels. Clinicians will complete this measure at the end of each intervention year. Dr. Will Aldridge, national leader in implementation science, from the Impact Center at the Frank Porter Graham Child Development Institute (in NC) will provide overall guidance on implementation issues encountered in the study. In particular, he will provide guidance on implementing the 6-component Partnership intervention in the real world environment of schools, with a view toward enhancing the scalability of the intervention, should analyses document expected positive outcomes.

Study Design.

Measures and Measurement Plan. All measures chosen for use in the study are in the public domain and have strong psychometric properties (e.g., internal consistency, test-retest reliability, concurrent validity). There will be two streams of data collection involving students. The first will be data collected to reflect school-wide impacts of the Partnership Condition focusing on academic record variables of students' grades, attendance, lateness and discipline referrals (including office discipline referrals and suspensions), and school climate. School-wide academic record data will be collected for all students and de-identified to the research team (it is considerably less burdensome for schools to share deidentified data for all students than to share for a sample of them). School climate data will be collected for a sample of about 60 students (3 randomly selected classrooms), and 25-40 staff (requesting all staff complete) at each of the 22 schools. School-wide academic record data will be collected once annually for the academic year prior to study start (2018-19), and will be collected each year for the three years of intervention vs. comparison, per procedures that we are replicating based on the current NIJ-funded RCT. Selected students and staff will complete the School Climate Survey (SCS) a free, online school climate survey from the US Department of Education (https://safesupportivelearning.ed.gov/edscls). The SCS is available as a web-based platform and includes a suite of school climate surveys for students, instructional staff, and non-instructional staff. Staff and students will be asked to

complete the survey, which assesses the dimensions of engagement, safety, and environment once annually at the end of each academic year for the four years of intervention vs. comparison (2019-20, 2020-21, 2021-22, 2022-23). Due to the COVID-19 pandemic, the team was unable to collect SCS data from students in [redacted] schools during the first academic year (2019-2020). While this means a compromised set of Year 1 data on school climate for the [redacted] site, such measurement is intact for SC, and we will still be able to document trends in time in school climate in [redacted] for years 2-4 of the intervention vs. comparison period. Additionally, the study team will collect rosters of classrooms receiving The Guide Curriculum (GC). This will enable two sets of analyses: first, we will document which students receiving Tier 3 services and participating fully in the study are exposed to GC and account for this in terms of interventions received in analyses. Second, this will significantly expand a second level of enrollment for the study, as we will have de-identified academic records for all students (related to recently approved amendments), and will explore impacts of the GC on academic record variables (e.g., discipline problems, grades, attendance) for students in classrooms in Partnership schools receiving it compared to students in demographically comparable classrooms from Wellness schools that do not receive it.

The second stream of data collection will focus on students receiving Tier 3 services and consenting to be in the study. Clinicians will collect these measures with students and families at intake, every three months, and at case closure, using an electronic data portal coordinated by Dr. Jihad Obeid and the Informatics Team at the Medical University of South Carolina (MUSC). The measurement strategy for each of the study aims is presented here:

Aim 1: Evaluate the impact of the Partnership enhancements in increasing the number of students and families receiving services and expressing satisfaction with them. For this primary aim, and per experiences from prior RCTs (18,19), as mentioned, we will collect data for each student on the number of sessions conducted by the SBH clinician in categories of assessment; individual, group and family therapy; case management; and teacher consultation. In addition, during the COVID-19 school closure period we will document which students receive any of these services through telehealth, and will document this form of service received. This will enable coding of overall productivity, for types of services, and for family involvement in care. To measure satisfaction with services, at the three month or case closure assessment points, we will collect the Client Satisfaction Questionairre-8 (CSQ-8) from students and parents. The CSQ-8 is a brief, widely used 8-item measure for use with youth aged 11 and older and adults (50).

Aim 2: Evaluate the impact of the Partnership enhancements on students' social, emotional/behavioral (EB), and academic outcomes. For this primary aim, there will be two sub-aims: Aim 2a will evaluate the impact of the Partnership enhancements on school-wide academic record variables of grades, attendance, lateness and discipline referrals. Aim 2b will focus on students receiving Tier 3 services and will assess their social and emotional/behavioral (EB) functioning. To assess social functioning, the Child and Adolescent Social and Adaptive Functioning Scale (51) will be completed by students. The CASAFS includes 24 items measuring students' functioning in four key social roles: school performance, peer relations, family relations, and home duties/self-care. Additionally, both "internalizing" EB problems, which include problems of depression, anxiety and exposure to trauma, and "externalizing" EB problems, which include conduct and attention problems, will be measured for students receiving Tier 3 services. Student EB functioning will be measured by parent and student report forms of the Brief Problem Checklist (52), a 12-item questionnaire that measures externalizing and internalizing problems. Derived from the comprehensive Child Behavior Checklist (53), it is designed for repeated periodic assessment of clinical progress, yielding both an internalizing and externalizing subscale (52). Please note that academic variables collected above school-wide for stream 1 data collection, will also be used for stream 2 data collection for students receiving Tier 3 services. Changes in the above variables will be assessed for students for the academic quarter before receiving mental health services and the academic quarter after services have been completed.

Additional Measures. In addition to measures directly reflecting study aims, secondary aims will be addressed by measures reflecting the potential impact of the two Partnership enhancements will be collected at the same time intervals for students receiving Tier 3 services. For the enhancement focused on mental health education and stigma reduction, students will complete The Guide Curriculum Assessment (GCA) reviewed previously (43,44). The GCA includes subscales assessing Mental Health Literacy in three dimensions: Mental Health Knowledge (MHK; 28 items),

Help Seeking (HS; 15 items), and Perceived Stigma (PS; 12 items). The MHK and PS subscales of the GCA have strong psychometric properties and will be used in the study. The MHK subscale includes 7 items on basic understanding of the brain, 9 items on common mental disorders, 7 items on stress and good mental health, and 5 items on causes of mental disorders and treatment. The PS subscale includes 5 items reflecting personal stigma (personal attitudes toward people contending with mental health problems) and 7 items reflecting social distance (the degree to which people are willing to accept people with mental health problems into regular social life). To further assess the reduction in Perceived Stigma, we will also collect the PS subscale from the GCA from parents of students receiving Tier 3 services within Stream 2 data collection using the teacher/parent version of the measure.

The enhancement focused on Family-School-Community Partnerships will be measured in three ways. First, the 24 SBH clinicians will complete the 63-item SBH Quality Assessment Tool (SBHQAT; 29) in August and May in each the four intervention versus comparison years (2019-20, 2020-21, 2021-22, 2022-23). Second, clinicians and students receiving Tier 3 services will complete the Therapeutic Alliance Scale for Children-revised (TASC; 55), a measure of therapeutic alliance across treatment. Third, as mentioned, family participation and engagement in their children's mental health treatment will be measured using the Parent Participation Engagement Measure (PPEM; 48), which assesses parent participation behaviors with the therapist as reported by both youth and their parents/guardians.

Data Management. The MUSC Informatics Team will work on a robust and secure data management infrastructure under the guidance of Dr. Obeid. The team will leverage an existing web-based tool, REDCap, to support data capture both in the field and across the collaborating institutions. REDCap (Research Electronic Data Capture) is a software toolset and workflow methodology for electronic collection and management of research projects that provides a secure, web-based flexible application, and includes real time validation rules with automated data type and range checks at the time of data entry. Exports are made available for several statistical packages including SPSS, SAS, STATA, R and Microsoft Excel. The underlying database will be hosted at the MUSC data center, a secure environment for data systems and servers on campus, and includes redundancy, failover capability, backups and extensive security checks. The system has several layers of protection including, user/group account management, *data access groups*, which allow data to be entered by multiple groups in one database with segmented user rights for entered data, audit trails for all changes, queries and reports, and Secure Sockets Layer (SSL) encryption. Case report forms (CRF), questionnaires and surveys for this project will be implemented in REDCap. The REDCap support team will work closely with the investigators to ensure the electronic CRF's operate correctly, validate error checks, create reports and oversee data export. The support team will also test the implementation over various client platforms including mobile devices such as iPads and/or Android tablets, and will manage accounts and access at other institutions and remote sites.

Analytic Plan. The proposed project is a cluster-randomized controlled trial (J=22 schools; 11 per treatment arm) comparing the efficacy of Wellness vs. Partnership services. As a general analytic plan, we will use hierarchical linear modeling (HLM) to evaluate the project aims. Specifically, we will use two-level HLM models to account for students being nested within schools. Though one might conceptualize this proposal as a three-level model (i.e., students nested within schools, and schools nested within sites), it would be neither feasible nor recommended to model site as a multilevel variable given there are only two sites in the design (56). In line with best practice, we will integrate site (i.e., SC vs. MD) as a covariate in the statistical models to contain any potential effects of this variable. Based on prior research conducted by the team, we expect intraclass correlations (ICCs) to warrant the incorporation of random intercepts to account for violations of independence. We will also test independence assumptions for the treatment parameters to determine how sensitive treatment effects are to potential violations of independence, and will include random slopes to account for nested treatment effects if ICCs exceed .01. For transparency, we will report both fixed and random effects (i.e. intercepts and slopes) of the model. Additionally, we will iteratively subset the model using a k-1 sensitivity analysis to determine the influence of individual sites on parameter estimates. We will estimate statistical models using full information maximum likelihood to accommodate any missing data (57). We will use maximum likelihood with robust standard errors to estimate models that include the Zero Inflated Poisson link function for count

outcomes (e.g. absences, referrals). This general analytic framework will be used in aims 1 and 2. Details, exceptions, and modifications to it are discussed below.

In addition to primary intent to treat analyses, we plan to use quasi-experimental methods to test dose-response, and treatment engagement on a core aspect of the Partnership Condition – the mental health literacy intervention through the program, The Guide. In Partnership schools, this intervention has continued to be implemented through all phases of the pandemic, going from virtual in some phases to in-person in classrooms. We are able to access student academic records (demographics, grades, attendance, discipline) for students in Partnership classrooms receiving The Guide, as well as students in comparable wellness classrooms not receiving it. Per below, we have a large sample size to pursue these supplementary analyses. In these analyses, we will be overpowered (MDES below .1) to understand the impact of this mental health literacy intervention on student functioning, including examining dose of intervention given variability in teachers' delivery of it. We also have broader school climate data to explore the impact of the Partnership intervention on this variable (collected fall, 2019; fall, 2020; fall, 2021; spring, 2022; and spring, 2023).

Model modifications for students receiving tier 3 services. To evaluate the effects of the enhanced treatment on students who receive tier 3 clinical services, and to accommodate the fact that there will be a rolling admission into clinical services, the treatment parameter will be interacted with a dosage parameter measuring each individual student's weeks of treatment received. This interaction term will provide a treatment effect estimate that is calibrated by dosage, as measured by weeks of treatment received. Because we will use an active treatment, we will be able to detect treatment-by-dosage differences between the enhanced and control treatments. To accommodate the possibility that random assignment does not create exactly equal groups with K=22, and to provide interpretable estimates of change in response to the intervention, we will use difference scores as the dependent variable unit of analysis for students receiving tier 3 clinical services. This will facilitate the direct examination of how services received over time influences youth change. The null hypothesis associated with change scores is that baseline differences remain constant and there would thus be no mean change across measurement occasions. Rogosa and colleagues (58-60) highlight the utility of using difference scores to evaluate pretest-posttest change in similar studies, indicating that previous work critical of this approach has been misleading in that it focused on several restrictive assumptions including high correlations of pretest and posttest measures as well as equal variances across measures over time. Given our previous research, outcomes, and statistical model, we believe that difference scores are the appropriate dependent variable.

Given the experiment will examine intent-to-treat effects in a real-world setting, we will conduct analyses to investigate variability in implementation and compliance to enhance causal effect interpretation of clients "as treated." Specifically, we will use a Bayesian Additive Regression Tree approach (BART; 61) to delineate the impact of key treatment assumptions (e.g., compliance, fidelity, etc.), as well as to estimate the impact of assumption violations on the estimation of causal effects in the design. BART is an extension of Classification and Regression Tree (CART) models that is based on a recursive partitioning algorithm that explains variation in the outcome through repeated splits of the data into homogenous subgroups that are similar on predictor variables. One significant strength of BART is that is capable of handling a large number of predictors and incorporates higher-order interactions that may be excluded from parametric analysis. Research indicates that BART is insensitive to tuning parameters and produces more accurate estimates of treatment effects compared to other methods of analyzing treatment effect heterogeneity (i.e., propensity score matching, propensity-weighted estimators, instrumental variable procedures, and regression adjustment; 61). Note that this BART enhancement to the randomized, experimental design should not be mistaken for a Bayesian trial design.

Power considerations. The design originally included a planned sample size of approximately N=2800 (1400 per arm) for Aims 1 and 2. We previously revised power estimates for these study aims that consider the possibility of reduced participant involvement given COVID-19 and recruitment challenges more broadly, with a revised sample size of approximately N=1400 (700 per arm). With the research study period concluding in June 2023, we have revised the enrollment projection to a conservative estimate of N=1225. With our currently active sites (J=22) and the total number of students enrolled in the study (N=1225, including expected spring 2023 enrollment), assuming 30% of variance

explained in the primary outcomes by pre-test covariates, and 80% power, we have a minimum detectable effect size (MDES) of .29. If we reach our goal of 1400 students, we will be at .28.

A priori power analyses indicate that we will be adequately powered to detect any primary outcome that has an effect size of d=.29 or greater (i.e., between small [d=.2] and medium [d=.5] in size per Cohen, 1988). Statistical software does not differentiate between one variable (e.g., depression) or another (e.g., anxiety) when executing power analysis for an outcome. Notably, Ferguson (2009) recommends that "minimum effect size representing a 'practically' significant effect for social science data" with difference measures like Cohen's d is .41.

Variation in cluster size is a typical (and expected) occurrence in cluster-randomized trials, with a priori power analyses invoking the projected average sample size per cluster for projected MDES estimates to accommodate differences in cluster size. Moreover, methodological literature has shown that any negative influence of cluster imbalance is limited to situations where there is a severe Pareto imbalance, defined as “a situation in which 80% of the subjects actually belong to only 20% of the clusters” (Guittet, Ravaud, & Giraudeau, 2006). This is not the situation here, and thus we expect the observed imbalance to have a negligible impact on analyses. Power analysis for the study corresponds to the ITT effect of the intervention, wherein the probability of the intervention’s ability to reject a null-hypothesis of no intervention effect is considered. Power estimates are not provided for the dose-response effect (i.e., the effect of treatment at varying dose levels) as this will be calculated using a Bayesian method (i.e., Bayesian Additive Regression Trees, BART).

Estimating dose-response effects using a conventional, frequentist treatment*dosage interaction would violate the strong ignorability assumption, confound effects with varying characteristics of participants and sites, and yield biased estimates (e.g., 69,70). The BART models proposed in the current application have demonstrated efficacy in estimating treatment effects in quasi-experimental studies that may vary as a function of a continuous variable, such as treatment dose (71). The BART approach will provide an estimate of the treatment effect for those who received the intervention conditional on baseline covariates (i.e., conditional treatment effect on treated). We will calculate conditional treatment effects on treatment for each individual following the Neyman-Rubin causal model (72,73). The BART models will yield an effect size for each varying level of exposure, as well as provide a credible interval (analogous to a frequentist confidence interval) for the effect estimate. The BART models will also allow missing data to be included as a feature in the predictive model using a “missingness incorporated in attributes” approach. This means that BART will use all available data. Kaplener and Bleich (74) demonstrated that this approach is computationally efficient and that results are comparable to other advanced missing data approaches (e.g., multiple imputation).

We will conduct additional analyses to ensure the results from our original models are not due to random noise in the sample. Specifically, we will conduct 250 Monte Carlo simulations in which a random binomial variable will be generated to represent an instrumental variable such that it will be uncorrelated with covariates or outcomes. Then we will regress each of the outcomes on the binomial variable yielding a parameter representing the relationship between the instrumental and binomial variable that is unrelated to the outcomes. This analysis will test the sensitivity of our BART models on estimated treatment effects and determine how robust our credible intervals are.

Please note, we will analyze data related to services received and outcomes for students of varying race/ethnicity as a supplemental, exploratory aim. Because of increased attention to cultural issues, it is possible that the Partnership intervention may have additional benefits in reducing disparities in services and outcomes for youth of color. Should findings indeed point to benefits of the Partnership intervention, these will be integrated into our dissemination plan and help to fuel critically important future research.

Study Population and Setting. Intervention will begin during the 2019-20 school year, and it will continue through the 2022-2023 school year. The study sample will include students from 22 middle schools, with 12 schools from SC and 10 from MD. One mental health center in each state will work with the study, with these mental health centers already having established relationships with the middle schools, with clinicians placed in these schools .7 FTE or 3.5 days per week. In MD, the site will be [redacted] (urban), with one school district and all 10 middle schools coming from this

site. In SC, the site will be [redacted] County (suburban and rural). Letters of support from mental health center leaders and the two school districts are included, reflecting the strong partnerships already established between the mental health centers and these districts.

Utilizing the demographic information available from each site's state Department of Education database, participating schools are predominately male (52%) and White (45%), followed by Black/African American (37%), Asian and Multiracial (3%), and less than one percent American Indian and Pacific Islander, with 12% identifying as Hispanic. Current prevalence estimates (2,14) predict that 20% of youth will meet criteria for a more serious EB problem. Due to random school assignment to condition, we predict these percentages will be evenly split across Wellness and Partnership.

As presented above, critical demographic factors will be assessed to investigate whether members of underrepresented groups present unique needs for services. Participant subgroups that will be further evaluated will include those varying based on mental health diagnosis, gender, race/ethnicity, and sociodemographic characteristics including income status, urban-rural-suburban status, and neighborhood levels of crime and violence. Initial analyses will be conducted to determine whether there are significant differences in primary outcomes of interest for subgroups compared to the overall sample. In instances where significant differences are found for a subgroup, interaction effects will be examined within a two-level HLM framework (see above) to further explore subgroup differences.

Recruitment Plan. School enrollment of each participating school was retrieved at the SC and MD state educational databases to determine the average middle school population is 600 across participating schools. In Year 1, around 12,000 students will attend the 20 study schools with an estimated additional 8,000 students entering study schools as 6th graders in Years 2 and 3, totaling 20,000 potential participants during the three-year implementation phase.

There will be two avenues of recruitment (with these strategies endorsed by the USC IRB). First, the Partnership enhancement is expected to lead to school-wide impacts and the study involves a systemic intervention involving no added risk to students and families; thus, school-wide collection of academic record variable is consistent with the research on education systems exemption from parental consent and student assess to collect these data. In terms of school-climate, staff completion of the climate measure has been determined to be exempt research with no requirement for consent since staff are anonymous and providing no personal information. For the randomly selected classrooms of students to complete the climate assessment, an opt-out procedure will be used. Students/families in the randomly selected classrooms will receive information on the study through multiple channels (mailed letters, letters sent home with students, emails) and will have multiple ways to opt-out (e.g., sending forms back, emailing the study team). All student record data will be de-identified prior to forwarding to the research team. These procedures are consistent with those currently being implemented in a large RCT led by the PI, which has had less than a 10% opt-out rate and no complaints from families thus far.

The second avenue of recruitment will be for students receiving Tier 3 treatment services. These students/parents will be consented using electronic consent (e-consent) in REDCap, with the consent form appended at the beginning of the survey. Participants and their parents will be required to go through the informed consent process and digitally sign the consent form using a mobile tablet device before proceeding into the survey questionnaire. MUSC has successfully piloted e-consent in REDCap with other IRB approved research studies. Given challenges with parents' ability to attend meetings at the school to complete the enrollment process, the study team developed protocol to allow for consent to be gained via phone and intake to be completed remotely via phone or computer. This flexibility allows enrollment to continue, and not be hampered by potential transportation or financial constraints that may otherwise prevent low-income families from participating. Additionally, as result of the COVID-19 crisis, procedures were developed to allow students to assent into the study via telephone or video conference. Students and parents may provide assent/consent via phone, after viewing consent materials and having the opportunity to ask questions of the clinician. Intake assessments can be completed verbally (via phone or video conference) or a link to complete surveys online may be sent via email or directly through the REDCap program by the clinician or research manager.

Based on current prevalence data, twenty percent (2,14) of students are expected to present with mental health challenges (n= 4,000). Of these students, based on the experience in similar studies the research team estimates that 30% will consent to participate representing the recruitment goal of 1,225 students by the end of the 2022-23 academic year. The rate of recruitment will be higher initially due to enrollment of students currently receiving services, however, over the course of the study an average of 35 students per month (during the academic year only, or four years times 9 months for 36 months total) will be enrolled. Note: significant changes to enrollment targets have been made during this project largely related to the unanticipated and unprecedented impact of the COVID-19 pandemic which temporarily closed school buildings and changed mental health care services starting in March 2020.

There are essentially six classes of student participants, with groups based on grade level at the start of the intervention vs. comparison (IvC) period of the study, which begins in the 2019-20 school year. There is a four-year IvC period, 2019-20, 2020-21, 2021-22, and 2022-23. Group A will be in the 6th grade in 2019-20, with students experiencing 1-3 years of services in this time interval. These students could have received services in 6th, 7th and/or 8th grades during the IvC period. Group B will be in the 7th grade in 2019-20, with students experiencing 1-2 years of services in this time interval. These students could have received services in 7th and/or 8th grades during the IvC period. Group C will be in the 8th grade in 2019-20, with students experiencing 1 year of services in this time interval. Group D will enter the study in 6th grade in 2020-21. Group E will enter the study in 6th grade in 2021-22. Group F will enter the study in 2022-2023 while in 6th grade.

Identifying eligible participants. Participants already receiving treatment and those newly referred for services will be eligible to participate and recruited by their SBH clinician. Throughout the implementation phase (years 1-4) each school will use their existing referral process to identify students in need of treatment which will be followed up and confirmed by the SBH clinician prior to enrolling them in the study.

Overcoming barriers to enrollment. In addition to our successful experiences with the opt-out procedure to be used for stream 1 data collection, both mental health centers have participated in extensive and similar research with the investigators leading this study. The SAB will provide input on the development of consent materials, and methods of communication, making sure that they are appealing. The process of utilizing e-consent will be convenient and streamlined for Tier 3 participants. Additionally, participant incentives are proposed, in the amount of $20 per parent assessment battery, and a token of appreciation for each student assessment battery to incentivize participation.

Study retention. Due to documented accessibility advantages of SBH (16) and our past experiences, Tier 3 students and parents are likely to remain involved in the study throughout the span of treatment. Additionally, the intervention requires no extra effort to participate outside of the assessments, with similar types of assessments routinely used in treatment for progress monitoring. In similar studies conducted, the most common reason for study attrition was due to students transferring to another school, which has been nominal across school wide populations. However, Tier 3 students experiencing EB problems are more likely to transfer schools than the general population.

Incorporating research activities into routine care. All research activities will be included in routine SBH functions. Consent to participate will be integrated into the existing process that clinicians use to obtain consent for treatment. Students and their parents may notice that their clinician is utilizing some new strategies, however all within parameters of expected clinical care. The same is true in the Partnership condition, will all enhancements those that would logically occur in a school embracing innovation and pursuing holistic strategies to remove barriers to student learning.

Training and experience of recruitment personnel. For students receiving Tier 3 services, the 20 clinicians will assist in study recruitment. Beginning in Year 2, a clinician was added in two [redacted] schools, one per condition for a total of 22 clinicians. Beginning in Year 3, two additional schools were added, one per condition, for a total of 22 schools and 24 clinicians. All clinicians will have a master's degree in a behavioral health discipline (e.g., psychology, counseling, social work) and will hold a valid license to provide psychological services or be under the supervision of a licensed clinician. Each clinician will participate in human subjects training prior to recruitment efforts and will be trained by the research team on recruitment procedures. The Lead Research Manager, Brooke Chehoski, will oversee recruitment efforts with the PI, Weist and Co-I/MD Site PI, Hoover, as guided by the SAB and building on experiences from prior RCTs conducted

by the research team, including a large current RCT funded by the National Institute of Justice that includes an opt-out procedure. See below for recruitment parameters.

Estimated number of potentially eligible study participants (describe how this number was determined [e.g., Electronic Health Record, claims data, clinic logs, administrative data, other]):	20,000
Total number of study participants expected to be screened:	20,000
Total number of study participants expected to be eligible of those screened:	4,000
Target sample size (use same number stated in milestones):	1225
If applicable, total number of practices or centers that will enroll participants:	22
Projected month first participant enrolled (month after project initiation):	9/2019
Projected month last participant enrolled (month after project initiation):	6/30/2023
Projected rate of enrollment (anticipated number enrolled per month of enrollment period):	42*

*Rate of enrollment is based on a 9-month time period reflecting the school year in years 1-4 for a total of 36 months. Recruiting 39 students per month over 36 months would give a total enrollment of 1,404 students.

(See appendix for site specific tables)

Sample Size and Power. Please see *Power considerations* for the study in the Analytic Plan above (p. 9-10), given we discuss these estimates alongside the Bayesian analytic strategy used for part of the analysis in the study.

Outcomes. We hypothesize that students/families in the Partnership condition will report increased positive outcomes compared to those receiving the Wellness intervention alone in the following ways: Improved connection to SBH services, longer service duration, and greater satisfaction with service; improved social, EB, and academic outcomes at post-testing as and sustained improvements in these dimensions in 9th grade. These outcomes are widely cited in SBH literature, and were validated by patients and stakeholders on the SAB and through research forums held throughout SC as part of the prior PCORI engagement award.

Site Selection. Proposed study sites were selected based on factors related to feasibility as well as their potential for providing a representative patient sample. Both the [redacted] Mental Health Center ([redacted]MHC) and the CSMH, have long histories of collaboration with investigators of this study. This existing relationship provides many benefits in avoiding common barriers to implementation. The two sites offer complementary demographics with CSMH serving youth who are primarily urban and African American, while [redacted] MHC serves a suburban and rural youth population that is more diverse racially and ethnically, and both sites serve low and middle income families, allowing us to evaluate for a variety of outcomes in subgroup populations. Additionally, incorporating the two interventions into routine SBH practices will facilitate findings that are immediately applicable to real world contexts.

Research Team and Environment

Research Team and Environment. This study represents a strong collaboration among faculty and staff from the University of South Carolina (USC), University of Maryland Baltimore (UMB), the Medical University of South Carolina (MUSC), and collaborating mental health centers and school districts at the two sites. All partners are strongly invested in the well-being of students in SC and MD and have the capacity to perform the work proposed in this application. Collaborating key personnel are:

Mark D. Weist (Principal Investigator, PI). The proposed study builds from a longstanding program of research by the PI (Weist) focusing on understanding and measuring quality in school behavioral health and developing and testing achievable evidence-based practices in schools, including two RCTs (R01s) funded by the National Institute of Mental Health (2003 – 06; 2010-15). In addition, the PI founded and directed the UMB Center for School Mental Health (CSMH) focused on advancing effective SBH in communities and states prior to moving to USC. The PI was an investigator on the Center for Adolescent Research in Schools (PI, Lee Kern) study funded by the Institute of Education Sciences (IES), an RCT that tested evidence-based classroom- and student-focused interventions. He is currently leading a large scale RCT in 24 schools funded by the National Institute of Justice (#2015-CK-BX-0018, 2016-2019), which aims to compare the effectiveness of 3 intervention conditions. This study has far exceeded its recruitment goals and has collected school record data, fidelity data, intervention receipt data, and student and teacher assessment batteries on approximately 15,000 students thus far. Dr. Weist is Professor of Clinical-Community, and School Psychology at USC and has directed both of these doctoral training programs. He leads the USC School Behavioral Health Team, which employs 11 staff members as well as a cadre of graduate and undergraduate students. The lab is comprised of 10 offices, 15 newer computers, a Teleform data entry system, a secure server space, and a variety of statistical software packages.

*Sharon Hoover (*Co-I/MD site-PI*).* As Co-Director of the CSMH and Associate Professor at UMB, Hoover is a leading national scholar on high quality SBH. Dr. Hoover has served as the PI, Site PI, or Co-I on several federally- and state-funded grants and contracts investigating the translation of children's evidence-based mental health practice into "real-world" settings, including: A National Institute of Justice (NIJ) Comprehensive School Safety grant; two National Institute of Mental Health R01s on Enhancing SMH Quality; a SAMHSA grant for a National Center for Safe and Supportive Learning Environments; two SAMHSA Systems of Care evaluations; two SAMHSA Healthy Transitions evaluations; and many more. Through significant local, state and national networks developed since the early 1990s, the CSMH has the potential to reach thousands of stakeholders from diverse disciplines with policy and research reports, enhancing the impact of the proposed study. The CSMH will utilize the resources made available to it from UMB and its extensive network to ensure that the needs of the proposed study are met.

Jihad Obeid (Co-I). Dr. Obeid is the Co-director of the Biomedical Informatics Center at MUSC, which serves the SC Translational Research Institute, and Health Sciences South Carolina at a statewide level. He is a pediatrician, formally trained in Informatics at the Division of Health Sciences and Technology, a joint Harvard-MIT fellowship program. He has extensive experience in research informatics, starting in 1998 as Director of the Pediatric research unit Informatics core at Weill-Cornell Medical College. At MUSC, Dr. Obeid oversees several academic and operational informatics initiatives and leads multiple Clinical and Translational Science Award-related Informatics projects such as the Research Data Warehouse, REDCap, Profiles research networking system, and many others. He is the division head for Biomedical Informatics in the Department of Public Health Sciences at MUSC. Dr. Obeid is a PI, informatics leader or Co-I on several NIH funded projects. Given his research background and leadership experience, Dr. Obeid will serve as Co-I and Informatics leader on this study. With the research team, he will oversee the development and implementation of a robust biomedical informatics infrastructure in support of the aims of the grant and will leverage existing web-based tools such as REDCap and data standards to support data capture and e-consent both in the field and on campuses across the collaborating institutions.

Amanda Fairchild (Co-I). Dr. Fairchild is an Associate Professor of Psychology at USC. As a quantitative psychologist, her research focuses on statistical design and analysis. Her methodological expertise focuses on statistical methods to optimize prevention and intervention research. The information technology facilities and other resources available to Dr. Fairchild and her research team will be made available to the PI throughout the duration of the project period. Dr. Fairchild will provide access to a variety of statistical software packages to support data analysis (Mplus, SAS, SPSS and R), as well as a multicore Dell applications server to support running software applications as needed.

Sam McQuillin (Co-I). Dr. McQuillin is an Assistant Professor at USC. His key contribution to the proposed project involves his work in the area of experimental design, quantitative methods, and implementation evaluation. His training is in school psychology with a quantitative psychology area of emphasis. As part of his research, he has designed, coordinated, and analyzed data from school-based randomized controlled trials, similar to the one in this project. He has served as a quantitative methodologist on a broad range of projects and has worked previously with school-based cluster randomized trials to be analyzed using hierarchical linear models and Bayesian additive regression designs, which are included in the current proposal.

Brittany Patterson (Co-I). Dr. Patterson is an Assistant Professor at UMB. She completed a pre-doctoral internship and postdoctoral fellowship at the CSMH. Dr. Patterson has provided training for administrators, educators, school police officers and student support staff on the impact of trauma on learning, secondary traumatic stress, and evidence-based mental health interventions for trauma-exposed youth. In addition, she helped develop and disseminate a toolkit of resources from the CSMH on civil unrest, and has worked with school and community partners to foster improved school-community-police relations, and to build trauma-informed multi-tiered systems of support in schools.

Robert Stevens (Consultant and Co-Chair of SAB). Dr. Stevens is a team member of the Carolinas Collaborative and Mid-South Clinical Data Research Network as well as a consultant on the recent PCORI engagement award to Dr. Weist and team. Dr. Steven's background as a former Director of Prevention and Intervention in a local school district has given him expertise in this area of research as well as an extensive network of connections with leaders of youth serving agencies across the state, which has been invaluable thus far in our patient and stakeholder engagement efforts.

June Greenlaw (Stakeholder Engagement Coordinator). Ms. Greenlaw has a graduate degree in community education providing excellent experience for her role on this project as an engagement specialist. She is also the manager of the Research Consortium on Children and Families which is comprised of 105 faculty members at USC. She served as the engagement specialist on the PCORI engagement award. In addition, Ms. Greenlaw is a parent caregiver of a youth contending with significant behavioral health issues.

Jenah Cason (Family and Youth Advocate). Ms. Cason has a master's in Social Work and serves as the Director of the Federation of Families for Children's Mental Health of SC. Ms. Cason has collaborated with the research team since 2010 when the SSBHC was in development. She is a Co-PI on a current Community Engaged Partners award with Weist's team which is evaluating the impact of an intervention to increase Youth Empowerment in SBH.

Beverly Griffin (Family and Youth Advocate). Ms. Griffin serves as a Parent Peer Support Provider and Family Advocate with the Federation of Families of South Carolina. Ms. Griffin will use her personal experience as a parent of a child with a mental health diagnosis and her professional experience to provide support to parent leaders who will be working within Partnership schools.

Christopher Haines (Director of School Mental Health Programs). Mr. Haines serves as the Director of School Mental Health Programs at the [redacted] Mental Health Center. Mr. Haines will assist in overseeing the activities of project clinicians at the SC site. Chris Haines, MS, LPC is the Director of School Mental Health Programs at [redacted] Mental Health Center. Chris's team includes 89 therapists stationed full time in South Carolina's largest school district. Chris is the School Mental Health Therapist at [redacted] School, where he has specialized in the treatment of adolescents with severe emotional and behavioral disorders for the past 11 years. Chris is on the South Carolina roster of clinicians trained in Trauma-Focused Cognitive Behavioral Therapy, a Master Trainer on Adverse Childhood Experiences, and a trauma-informed trainer through the Community Resilience Initiative. Chris speaks across the state and the region on trauma-informed school practices and the development and leadership of effective school mental

health programs. With a leading role in school mental health, Chris has been a partner to his school and his District in developing multi-tiered systems of support for the social/emotional and behavioral needs of students.

Jennifer Cox (Program Director, University of Maryland, School Mental Health Program). Ms. Cox is the Program Director and a senior Lead Clinician for the University of Maryland, School Mental Health Program (SMHP), a program whose mission is to enhance the learning environment of [redacted] Public schools by removing the barriers to learning and actively promoting the social-emotional-behavioral well-being of students. Ms. Cox has over a decade of experience providing clinical services, resources, training and consultation across a multi-tiered system of supports. She provides administrative and clinical oversight to 25 SMHP schools and has worked to expand the SMHP tele-mental health program to increase psychiatry services and access in schools. Ms. Cox has a Certificate in Infant and Early Childhood Mental Health, is a board approved supervisor for social workers and is a state-wide trainer for Botvin's LifeSkills. Her work in schools, specifically with evidence-based practices and parental involvement in school, has been published and recognized by the field. She was the recipient of the National Association of Social Workers (NASW) Field Instructor of the Year Award and presents at local, state, and national levels. Most importantly, she is the wife to a fantastic husband and mother to two amazing boys.

DISSEMINATION AND IMPLEMENTATION POTENTIAL

A. Building on the platform of the ECHO program (25, 26) and guidance by the Stakeholder Advisory Board (SAB), dissemination of study findings will begin in Year 5, with comparison schools joining ongoing ECHO clinics held for intervention schools (in Years 1-4). In Year 5, parent leaders and the study team will conduct presentations to each of the 22 schools, the sponsoring school districts, and the two mental health centers, reviewing study findings and making them accessible through the study website. Signs about the study and its findings will be posted throughout the centers so that patients and families receiving treatment within them can learn about the study. In addition, study notifications and consent/assent forms for families will mention the study website and availability of findings as of Spring 2023, and our hope is that study participants access these resources to learn about study findings and lessons learned. In addition, we will make available as a public domain resource and broadly disseminate the study implementation manual, increasing the ability of other sites to implement the six-component Partnership intervention. Further, in Year 5, the ECHO platform will be used for sharing of findings and dialogue with professional organizations (e.g., National Association of School Psychologists, National Council for Behavioral Health), and state, local and federal policy leaders. Our connections to state and national groups with a vested interest in school behavioral health (SBH) will be facilitated by networks the PI and Co-I/MD site-PI lead, in particular, the Southeastern School Behavioral Health Community (SSBHC, see www.schoolbehavioralhealth.org) and the Center for School Mental Health (CSMH, see http://csmh.umaryland.edu), with an anticipated reach to more than 100,000 stakeholders by study end. More than 26,000 schools in the nation are implementing MTSS, as in systems such as Positive Behavioral Interventions and Supports (PBIS, see www.pbis.org). Within these efforts, there is increasing priority on effective SBH (17). The CSMH reports a dramatic increase in technical assistance requests for evidence-based mental health practice implementation in schools, with a marked uptick following incidents of mass violence in schools. With certainty, national centers for SBH and PBIS will use findings from the proposed study in their ongoing work to expand and improve the quality of SBH and MTSS in the U.S., and these centers have close working relationships with the professional organizations and networks mentioned, and many others.

Please also note that the PI, Co-I/MD site-PI and research team have significant publication records in the SBH area, with publications reflecting breadth in outlets of peer-reviewed empirical articles and reviews, books and book chapters, monographs, widely disseminated white papers, e-books, research briefs, newsletters and others. As an example, for the recently completed PCORI Engagement Award, the PI and SAB co-chair led a series of 4 issues (the entire 2017 volume) of the Report on Emotional & Behavioral Disorders in Youth, including 15 articles focused on ways to increase the effectiveness of stakeholder driven SBH (75-78). With significant input from the SAB, user-friendly briefs on study findings and lessons learned will be developed and improved after each year, and finalized and broadly disseminated in Years 4 and 5 of the study via the SSBHC and CSMH networks and others the study team is connected to (see www.carolinanetwork.org, www.pbis.org , www.smhile.com).

B. Three prominent barriers to disseminating and implementing results from this study in other settings are federalism, information management challenges, and discipline and youth-serving system silos. Federalism. A major issue affecting the scaling up of evidence-based strategies to improve student functioning is federalism, including the emphasis on states' rights and local control, which can result in highly variable experiences across communities and states, and even within them (79). To address this challenge, in our work we have emphasized a community of practice approach (80), and effectively convening groups at local and state levels to support the increasing coherence and impact of SBH initiatives, as in the work occurring through the SSBHC and CSMH. In particular, states play a crucial role in overcoming the challenge of federalism, when they assume liaison roles between federal and national initiatives and support, and experiences and resources from other states, and getting information and resources down to counties/school districts, and in turn tracking and disseminating information on best practices occurring at local levels. Overcoming challenges of federalism has been a major focus of the CSMH; PI, Weist, and Co-I and Maryland Site PI, Hoover. Both the CSMH and the SSBHC offer opportunities for state leaders to present and share innovative initiatives during national and regional conferences and webinars, with explicit support for promoting cross-state innovation adoption. We are confident that these methods will help to overcome the challenge of federalism, and provide an important national exemplar on accomplishing the same. Information Management. Rapidly managing diverse sources of information through diverse media is an increasing challenge (81). We will help diverse stakeholders use information from the study by developing materials in multiple and user-friendly formats as in the above broad array of strategies planned for dissemination, repetitiveness in sharing key messages, and identifying and publicizing the experiences of exemplar sites, and their experiences in moving toward greater effectiveness and impact. Two specific strategies that have been employed by our team are Playbooks and Infographics. To date, the CSMH has published two Playbooks that succinctly review best practices and tips from the field on critical practice strategies. The two published playbooks (School Mental Health Screening, School Mental Health Teaming) shared lessons from the field on how to implement tested strategies for practice improvement, with easily understandable text and language and ready-to-use tools. For example, the Teaming playbook includes action steps for schools and communities to engage in community-partnered SBH models, with templates for memoranda of understanding between schools and communities and tools to define roles and responsibilities of school- and community-employed support staff. Infographics have also been used by the CSMH as a tool for communicating the need for and value of providing mental health services in schools. These types of communication tools will be used to communicate findings from the proposed study in a manner that is easily digestible and usable by others in the field. Discipline and Youth-Serving System Silos. An unfortunate reality is that discipline and youth-serving systems often operate in isolation (16). Since the SBH field is inherently interdisciplinary, and operates in the nexus of many systems, efforts may be impeded when disciplines and systems fail to interact meaningfully. As above, to address this challenge, we will connect to the SSBHC, CSMH and other communities of practice, and develop a range of interactive information sharing strategies, distilling information down into user-friendly briefs and infographics, and using a range of approaches (ECHO video conferencing, professional presentations, smaller meetings and discussion forums) to move discussions to dialogue, collaboration, and positive policy change as guided by the SAB and PCORI project officers. We look forward to discussions with and active guidance from PCORI project officers on building strategies for meaningful interdisciplinary and cross-system collaboration to advance effective SBH initiatives

and to share lessons learned and findings from exemplary initiatives as in the intervention tested in the proposed study.

PROTECTION OF HUMAN SUBJECTS.

Twenty-two middle schools (12 in South Carolina and 10 in Maryland) will participate in a cluster-randomized controlled trial with stratified random assignment used to assign schools to the Wellness Group or the Partnership Group for a 5-year longitudinal study. These schools will be from two school districts including urban and suburban (MD), and rural and rural/suburban (SC) sites. Schools will utilize existing referral processes for identifying students in need of Tier 3 services. Critical demographic factors will be assessed to investigate whether members of underrepresented groups present a unique need for services. It is estimated that over the course of the study, approximately 4,000 students/families will be eligible to participate, and about 30% will provide assent/consent. Thus, student participants will include an estimated 1,225 youth (approximately 612 in each condition) across 12 middle schools in South Carolina and 10 middle schools in Maryland. Students may participate in the sixth through eighth grades. The two interventions being evaluated are systemic and will be a part of normal educational or therapeutic treatment that the students would ordinarily receive. Students receiving Tier 3 services and their parents will be consented to provide assessment batteries at in-take and every three months during treatment. For students not receiving treatment with a clinician, researchers will implement an opt-out procedure, informing students and their parents that researchers will be collecting de-identified school records and climate survey on students in the school and that they may choose to opt out if they desire. Significant collaboration with the SAB will occur to ensure the protection of participants' privacy and confidentiality.

Potential Risks. Risks for participants (all students in the 22 participating schools) are minimal, with the greatest risk being the release of confidential information, and boredom from completing routine assessments. Students who receive individual counseling by a clinician will complete some items of a sensitive nature, and may feel uncomfortable with surveys. Strict protections will be in place per procedures of the experienced research team for assuring student confidentiality and privacy. There is also a risk that the study will identify students with urgent emotional/behavioral issues and need for urgent services, which will be provided by mental health providers in the schools.

Recruitment and Informed Consent. Participation occurs at two different levels- school wide participation where involvement includes typical educational activities (e.g., completing the climate survey) and the release of de-identified school record data. As above, academic record data will be collected school-wide without parental consent/student assent related to the education systems research exemption for the collection of these data. For the school climate measure, an opt-out procedure will be in place where parents receive a letter taken home by students, as well as email announcements about the study. Each letter will provide instructions for how to opt-out of the study, including by email and calling the study team. Additionally, students receiving therapeutic counseling at school (referrals for counseling will follow established mechanisms already in place to refer students for services) and their parents will be informed of the study (by their clinician) and will have the option to consent to participate in the study which will be integrated into the typical consent for treatment process that is required by mental health providers.

Protections Against Risk. The study team has significant experience in implementing data collection, management, and analyses processes and the physical and personnel resources to carry out these procedures. Per other active studies, data will be stored and managed at MUSC and USC and transported through confidential correspondences with research personnel collaborating with the participating schools. For each of the research aims, all data will be confidential, with strict protections on privacy. All information obtained will be stored in locked file cabinets in a locked room at MUSC and USC. Interventions evaluated in this study do not represent more than a minimal risk and therefore monitoring by the PI and IRB is presumed sufficient. Should PCORI program staff or the IRB recommend a Data Safety Monitoring Board, one will be established prior to study start.

Potential Benefits of the Proposed Research to Human Subjects and Others. Team member participants are likely to benefit from involvement in the study by increased knowledge of utilizing data to inform decision making, significantly involving patients and stakeholders in shaping care, and gaining experience with a range of evidence-based practices.

Furthermore, students who receive SBH programs and services within the Wellness and Partnership conditions are likely to experience benefits in functioning.

Importance of the Knowledge to be Gained. Through qualitative research supported by a recently completed PCORI Eugene Washington Engagement award, two critical enhancements to SBH services were identified by patients and stakeholders to: 1) Enhance mental health literacy and systematically reduce stigma for SBH, and 2) increase partnerships among youth, families, schools and clinicians. For both of these critical enhancements the research team has carefully identified evidence-based interventions that will augment the existing evidence-based CSS framework for SBH. We hypothesize the Partnership condition will be a feasible intervention and will make services more appealing, acceptable, less stigmatizing and effective, and will assist in further building support for SBH and its significant access and effectiveness advantages for behavioral healthcare. Findings from this study will be widely disseminated throughout the southeast region and the U.S. through dissemination resources of USC and UMB that currently reach more than 60,000 diverse stakeholders. With networks of both teams growing steadily, we expect by study completion that this number will be around 100,000 stakeholders. Findings will provide education and mental health/health care leaders with a framework for maximizing patient connection to accessible and evidence-based SBH and thus increase the positive impact of these services for youth, families and schools.

Inclusion of Women and Minorities. All students in grades 6-8 across the 22 middle schools, who give assent/consent to participate either by informed consent or opt-out procedure, will be allowed to participate; this includes children/families of various social/cultural, racial and socioeconomic backgrounds. Analyses will account for differences in participant characteristics that may influence differential responses to services or degree of specific symptom presentation.

Inclusion of Children. Children in grades sixth through eighth grade (typically 11-15 years old) of various social/cultural, racial and socioeconomic backgrounds will be eligible to participate in the study. Analyses will account for differences in participant characteristics that may influence differential responses to treatment or degree of specific symptom presentation. The research team has significant experience in working with children and adolescents in the mental health context, particularly in the context of serving youth mental health needs within the school arena. As above, the PI, Mark Weist, is a licensed clinical psychologist who is specially trained in the area of child, adolescent and school mental health, with more than 25 years of experience in research and active practice. Clinicians providing evidence-based intervention in schools all have specialty training in child, adolescent and family mental health, and the participating school sites are staffed and supported to meet the full array of student mental health needs.

Estimated Final Racial/Ethnic and Gender Enrollment Table:

Race	Male (N)	Female (N)	Total (N)
American Indian/Alaska Native	2	2	4
Asian	20	19	39
Black/African American	266	250	516
Hawaiian/Pacific Islander	2	1	3
White	325	304	629
Multiracial	24	21	45
Hispanic (Latino/Latina)	85	79	164

CONSORTIUM CONTRACTUAL ARRANGEMENTS

University of Maryland Baltimore

The Center for School Mental Health (CSMH) house at the University of Maryland Baltimore will serve as a project site, and will implement the Wellness and Partnership interventions in ten schools in Baltimore, MD. The CSMH provides therapeutic services in schools and will dedicate ten clinicians and two senior trainers to this project with an expected effort of one day per week. UMB will coordinate all project activities at the 10 schools with the [redacted] City School District.

Dr. Sharon Hoover is an Associate Professor and the Co-Director of the CSMH. She will serve as a Co-Investigator and Site PI for the Maryland Site. She has served as the PI, Co-Investigator, or Lead Evaluator on federal and state grants investigating school mental health systems and interventions, including two SAMHSA Systems of Care grants; a SAMHSA Awareness, Wellness and Resilience in Education evaluation; and two National Institute of Mental Health R01s on Enhancing School Mental Health Quality. Dr. Hoover will be responsible for overseeing all grant activities in the Maryland Site, including implementation of all intervention components, collection of measures, and active engagement of stakeholder advisors. She will assist in interpretation of findings, writing of papers and reports, and dissemination.

Dr. Brittany Patterson is a Psychologist and Assistant Professor in the CSMH. She will serve as a Co-I and Senior Trainer for the Partnership group. Dr. Patterson's research focuses on mental health in underserved schools and communities and she has served as a clinician in the [redacted] City schools for three years. Dr. Patterson has considerable training experience, serving as the CSMH lead trainer for trauma-informed schools and safe and supportive learning environments and providing technical assistance for the U.S. Department of Education's Promoting Student Resilience (PSR) grantees. Dr. Patterson will lead the training and implementation support for the Partnership group, and will spearhead engagement with local stakeholders, including patients and families. She will assist in writing of papers and reports and dissemination.

Medical University of South Carolina

Dr. Jihad Obeid and team are national leaders in informatics and data management as well as patient/participant recruitment and integration of consent into on-line measurement collection, with a significant history of NIH and PCORI funding. Dr. Obeid will serve as a Co-I and Informatics leader on this proposal. Under this proposal, the MUSC team will work to develop a robust biomedical informatics infrastructure in support of the aims of the grant. The team will leverage an existing web-based tool to support data capture both in the field and on campuses across the collaborating institutions. REDCap provides secure, web-based flexible applications, including real time validation rules with automated data type and range checks at the time of entry. The database will be hosted at MUSC and confidentially shared with USC. The MUSC team will provide project management and support in the planning, and development of various databases, case report forms and surveys implemented in REDCap as needed. This team will work closely with the investigators to ensure the electronic forms operate correctly, validate error checks, create reports and oversee data export. The MUSC team will manage accounts and data access at other institutions and remote sites and will test the implementation over various client platforms including mobile devices such as iPads and/or android tablets.

South Carolina Department of Mental Health

The South Carolina Department of Mental Health (SCDMH) was chosen to participate in this project as the leader of SBH services in SC (and collaborator with the PI and research team in developing the core Wellness intervention implemented in all sites). The SCDMH will support this project through their statewide quality improvement efforts. The SCDMH has an interest in amplifying patient engagement in behavioral healthcare and strongly endorse the amplified benefits of the Partnership enhancements added to the Wellness intervention (see letter from Mr. Magill, State Director). All 14 clinicians in the 12 middle schools in the study will receiving training and support in the Wellness intervention and 6 (randomly assigned) will receive the Partnership enhancement to this intervention. In addition, two senior trainers, 1 for the Wellness Group and 1 for the Partnership Group will support intervention implementation. The

study will operate with the major partner, the [redacted] Mental Health Center, a leading site for the delivery of SBH within the SCDMH system. The SCDMH will commit personnel as outlined in their budget for 12 employees.

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Appendix

Table 1

Descriptive Statistics of Wellness + Partnership Component

Wellness + Partnership Components	N	Min	Max	Mean	SD
Assuring families are strongly involved in services	**92**	**2**	**6**	**5.6**	**.79**
School Administrators	6	5	6	5.8	.41
Educators	12	2	6	5.0	1.48
School Counselors	18	5	6	5.8	.43
School-Based Clinicians	32	4	6	5.7	.63
Psychologists and Research Staff	10	4	6	5.4	.84
Community/Family Organizations	5	5	6	5.6	.55
Taking steps to reduce the stigma of services	**91**	**2**	**6**	**5.5**	**.85**
School Administrators	6	4	6	5.5	.84
Educators	12	2	6	5.0	1.35
School Counselors	18	5	6	5.8	.43
School-Based Clinicians	32	4	6	5.6	.72
Psychologists and Research Staff	10	4	6	5.4	.84
Community/Family Organizations	5	6	6	6.0	0
Implementing services shown to be effective	**90**	**4**	**6**	**5.7**	**.57**
School Administrators	6	5	6	5.7	.52
Educators	12	4	6	5.5	.80
School Counselors	17	5	6	5.9	.33
School-Based Clinicians	32	4	6	5.6	.61
Psychologists and Research Staff	10	5	6	5.9	.32
Community/Family Organizations	5	5	6	5.8	.45
Assuring that services are of high quality	**88**	**4**	**6**	**5.7**	**.52**
School Administrators	6	6	6	6	0
Educators	12	4	6	5.3	.78
School Counselors	18	5	6	5.9	.32
School-Based Clinicians	29	5	6	5.7	.46
Psychologists and Research Staff	10	5	6	5.8	.42
Community/Family Organizations	5	6	6	6.0	0
Supporting staff for high quality implementation	**89**	**4**	**6**	**5.8**	**.48**
School Administrators	6	5	6	5.7	.52
Educators	12	4	6	5.3	.65
School Counselors	18	5	6	5.9	.32
School-Based Clinicians	3	5	6	5.8	.38
Psychologists and Research Staff	10	5	6	5.9	.32
Community/Family Organizations	5	6	6	6.0	0
Promoting school-family partnerships	**90**	**2**	**6**	**5.7**	**.69**

School Administrators	6	5	6	5.8	.41
Educators	12	2	6	5.3	1.23
School Counselors	17	5	6	5.9	.33
School-Based Clinicians	32	4	6	5.7	.65
Psychologists and Research Staff	10	5	6	5.7	.48
Community/Family Organizations	5	5	6	5.8	.45
TOTAL 6 ITEM Wellness + Partnership SCALE AVERAGES	**90**	**3.2**	**6**	**5.7**	**.54**

Table 2

Descriptive Statistics of Comparison Components

Role	Number	Percent of Total
School Administrators	81	15.3%
Educators	75	14.2%
School Counselors	143	27.1%
Clinicians (Social Workers, Behavioral Specialists, DMH school-based clinicians, etc.)	63	11.9%
Psychologists (all non-university employed psychologists)	20	3.8%
University Faculty/Staff (includes University employed psychologists)	54	10.2%
University Students	42	8.0%
Community/Family Organizations	42	8.0%
Parents	5	1%
School Nurses	1	<1%
School Resource Officers	2	<1%
Total	528	100%

Table 3

SAB – SC Team

Name	Organization	Subgroup
Louise Johnson	SC Department of Mental Health	MH/Community Partners
John Payne	SC Department of Education	Education
Lori Chappelle	Waccamaw Mental Health Clinic	MH/Community Partners
Robert Hock	University of SC- Community Partnerships	MH/Community Partners
Leshawn Hiers	Youth patient	Patients and Families
Jenah Cason	Federation of Families	Patients and Families
Beverly Griffin	Federation of Families	Patients and Families
June Headley-Greenlaw	Patient caregiver/Engagement Specialist	Patients and Families
Bev McCarty	Patient caregiver	Patients and Families
Erika Kirby	Blue Cross Blue Shield Foundation of SC	
Pete Liggett	SC Department of Health and Human Services	
Rob Rhodes	SC school staff in study	Education
Alice Matthews	SC parent of a child in study	Patients and Families

Table 4

SAB – MD Team

Name	Organization	Subgroup
Rev. Al Hathaway	MH/Community	MH/Community Partners
Shanda Crowder	Family League of Baltimore	Patients and Families
Deborah Badawi	University of Maryland Pediatrics	MH/Community Partners
Felicia Taylor	Patient caregiver	Patients and Families
Susan Tager	Patient caregiver	Patients and Families
Michael Wills	New Lens	MH/Community Partners
Terry Patton	Retired MD teacher	Education
Nisha Sachdev	Bainum Foundation	
Valerie Conaway	MD parent of a child in study	Patients and Families
James Padden	[redacted] Schools	

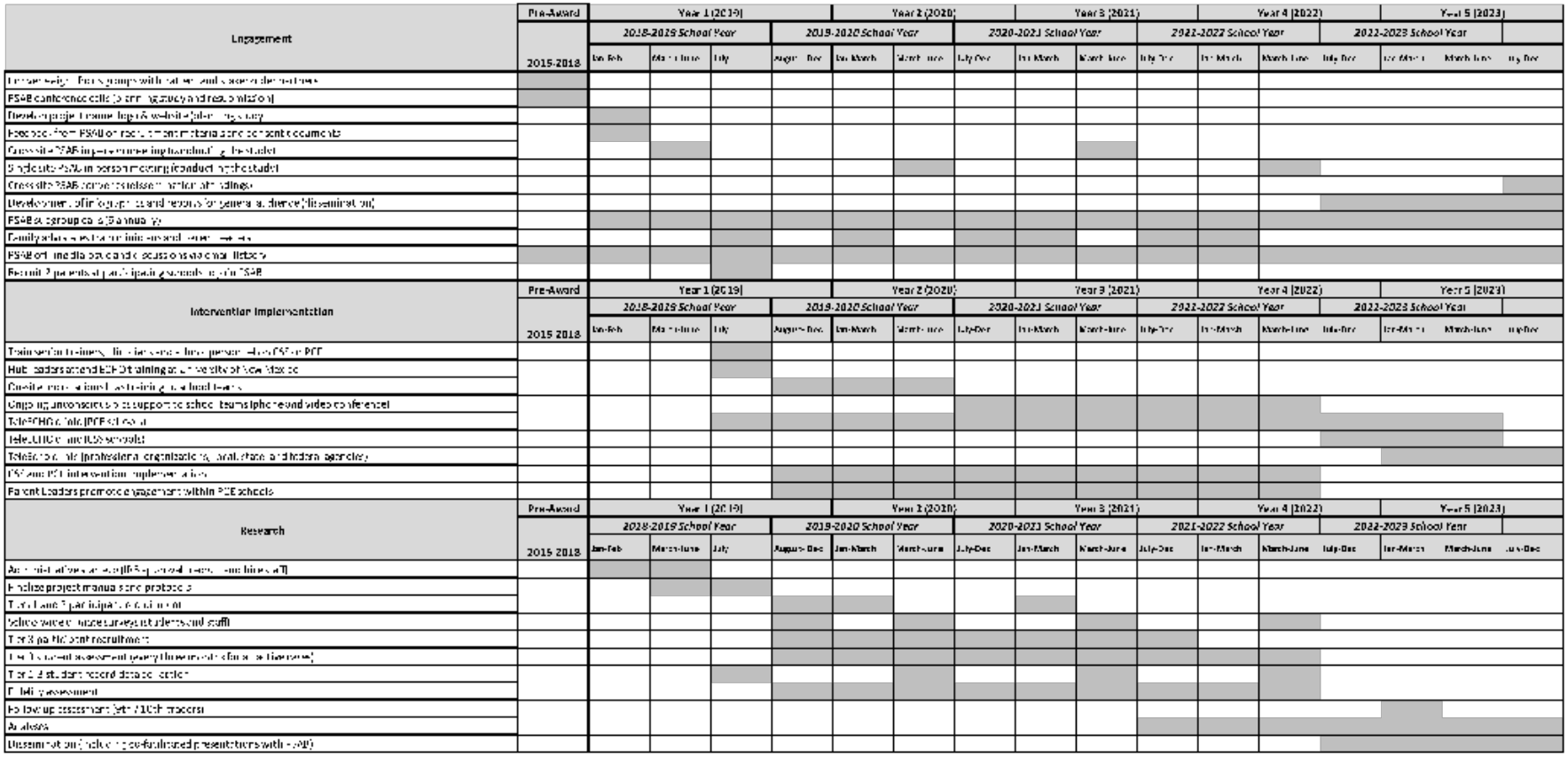

Figure 1. Gantt chart of study.

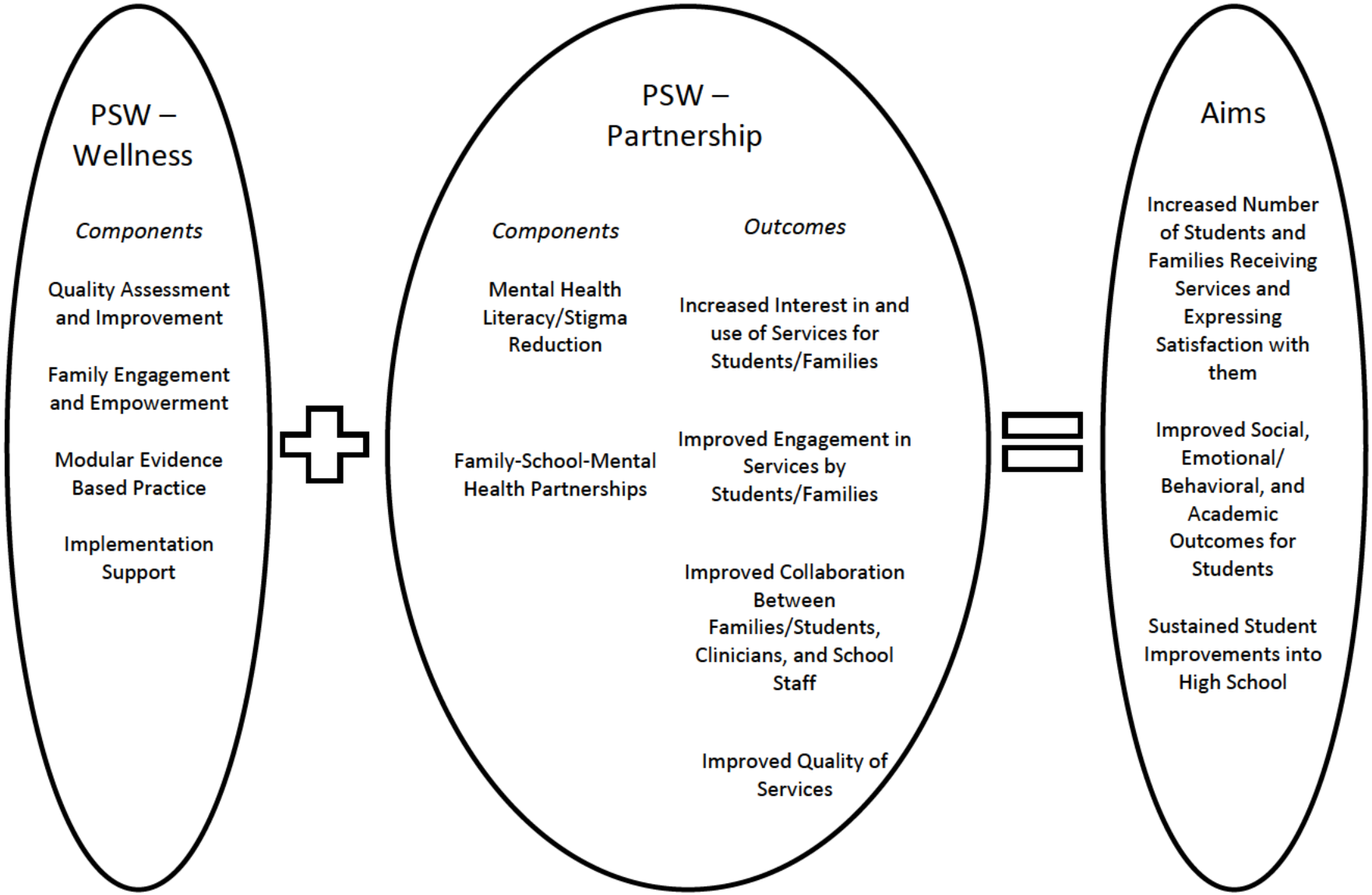

Figure 2. *Theory of change.*

Preservation of notes regarding Study Aim 3, removed in the May 2023 contract modification:

The original research plan included a third study aim: Evaluate the follow-up effects of the intervention on social, EB, academic and health outcomes in a sample of students followed into high school. This aim was removed in a subsequent revision of the research plan (May 2023) due to significant challenges in contacting students who have been transferred to a new therapist in high school or who have been discharged from services. Additional references to Aim 3 have been removed from this plan to reduce confusion, but will be preserved in the appendix.

Year 5 of the project (2022-2023) included plans to collect follow-up data from students who previously enrolled during middle school but had since moved on to 9th or 10th grades. The purpose of this follow-up timepoint was to discern whether students who were part of the Partnership condition sustained any improvements in social, emotional/behavioral, and academic functioning after transitioning to high school. Measures collected during follow-up in middle school would be used for follow-up for eligible students in 9th or 10th grade during the 2022-2023 school year.