CORE 3: PRINCIPAL RESEARCH CORE (Dr. Leaf, Director; Drs. Bradshaw & Ialongo, Co-Directors)

1. OVERARCHING AIM OF THE PRINCIPAL RESEARCH CORE
As previously described, the overall mission of the Johns Hopkins Center for Prevention and Early Intervention (JHU CPEI) is to develop, test feasibility and acceptability, implement, evaluate, and disseminate research and research methodologies to improve the outcomes of elementary and middle school-based preventive and early interventions aimed at reducing aggressive and disruptive behavior in children and youth. The JHU CPEI seeks to aid our nation’s efforts to reduce the incidence and prevalence of children’s mental/behavioral disorders and associated impairments by aiding local schools and communities (1) in creating supportive learning environments for all students and (2) seamlessly linking children and youth not responding to universal interventions with indicated preventive interventions. To accomplish this task, we need more effective interventions and guidance concerning the design of research, the interpretation of data, and the targeting of interventions to those most likely to benefit. This is best accomplished when methodologists work closely with interventionists and both have access to policy makers and providers. We have previously described (see Research Methods Core) the initiatives we will undertake to meet the methodological challenges of effectiveness research in schools. We now describe the specific feasibility and pilot intervention Initiatives for which we are requesting funds. The activities proposed here benefit considerably from the 23-year academic/community partnership with the Baltimore City Public School System (BCPSS).

The specific aims of the Principal Research Core (PRC) are to:

Aim 1: Conduct research on the intersection between efficacy and effectiveness research to optimize program outcomes in real-world settings.

Aim 2: Develop a continuum of evidence-based preventive interventions for the elementary and middle school years.

Aim 3: Conduct pilot and feasibility studies in preparation for RO1 funded effectiveness trials of evidence-based prevention and treatment interventions and their combination for children and adolescents.

2. BACKGROUND AND SIGNIFICANCE
There is a need to move from efficacy to effectiveness research. Researchers affiliated with the JHU CPEI have a long history of conducting research on the intersection between efficacy (e.g., randomization of teachers and students at the level of classroom, within school controls, rigorous training of teachers and mental health professionals, and intervention manuals) and effectiveness (e.g., the absence of participant exclusion criteria, the teachers and other interveners were employees of the schools, not randomly assigned) (e.g., Ialongo et al., 2001; Bradshaw et al., in press). Recent research reviews of efficacy studies document the growing number of preventive interventions that either reduce the onset of common mental disorders or decrease the duration and disability of initial episodes of these disorders (Burns et al., 2002; Coie et al., 1993; Greenberg et al., 1999, 2001; Hawkins & Catalano, 2004; Kazdin, 2000; National Advisory Mental Health Council’s Services Research and Clinical Epidemiology Workgroup, 2006; Olds et al., 1999; Rones & Hoagwood, 2000; SAMHSA, 2007; Weisz et al., 2005; Wilson & Lipsey, 2007). Federal initiatives (e.g., Safe Schools/Healthy Students and the Safe and Drug Free School Program) require applicants to use empirically validated interventions. Despite the large number of efficacy studies that demonstrate effective prevention or problem reduction when treated early, few studies examine (1) whether efficacious programs exhibit equally positive outcomes when implemented in natural service/treatment settings; (2) how dosage and quality of implementation affect outcomes; (3) how different program models and training strategies affect outcomes; and (4) the conditions necessary for successful program outcomes in natural settings with local ownership of the intervention process (Mrazek & Haggerty, 1994). The next challenge facing prevention and intervention scientists is to help practitioners put effectively “proven programs” into practice and achieve the same outcomes as observed in research studies.

There is a continuing need for research on the combination of evidence-based and promising universal interventions. In addition to the aim of moving from efficacy to effectiveness, we will continue to address the need for integrated prevention models that seamlessly combine different types of universal interventions at the elementary school level (K-5). Currently, there is little integration between models and thus schools are not able to systematically integrate different universal program strategies (e.g., school-wide discipline, individual teacher support for classroom management, social-emotional learning programs). Neither developers nor services researchers have made substantial effort to integrate programs and develop combined packages that schools can implement. We began this work in our current ACISR with an innovative model that integrates the Good Behavior Game (GBG; Barrish et al., 1969) and Promoting Alternative Thinking Strategies (PATHS; Greenberg & Kusche, 2004) (referred to as GBG+ PATHS). Strong pilot findings under ACISR funding has led us to recently receive funding from the Institute of Education Sciences (IES) for a 27-school, randomized controlled evaluation of
GBG+PATHS versus GBG alone and standard setting (control). The proposed school-based intervention work we now propose includes pilot testing of the combination of complimentary, evidenced-based, universal interventions. As described in PRC Initiative 1, we are proposing to combine Positive Behavior Intervention Supports (PBIS; Sugai & Horner, 2006) and Classroom Checkup (CCU; Reinke et al., 2007) with the GBG+PATHS combination. We expect that the combination of PBIS and CCU should further improve teacher implementation of GBG+PATHS and in turn increase their impact on early aggressive and, later antisocial behavior, substance abuse, and depression.

There is a need for universal, selective, and indicated preventive interventions at multiple developmental periods. While continuing to focus on the elementary school years, K to grade 5, we are proposing to extend our intervention efforts to the middle school years. This new focus on middle school years, as reflected in PRC Initiatives 2-4, focuses on the further development of anti-social behavior that is shown by both “early” and “late starter” models as described by Patterson et al. (1992) and others (Moffitt, 1993). According to Patterson and colleagues, there are at least two major pathways or trajectories to serious antisocial behavior, substance abuse, and academic failure (also see Moffitt, 1993). The “early starter” trajectory begins in the toddler years, when parental success in teaching their child to interact within a normal range of compliance and aversive behavior is a prerequisite for the child’s healthy social development. The second pathway - the “late starters” - characterizes the relatively high prevalence of late onset antisocial behavior and academic failure in the middle school years. Given the high rate of adolescent aggression, delinquency and school failure in high-risk urban environments, developing both universal and indicated interventions in the middle school years are essential to the reduction in disruptive aggression, delinquency, and school failure/drop-out. In the middle-school period programs are needed that both support teachers and schools to create safe and orderly school and classroom environments, further teach essential social and emotional skills (i.e. skills in emotion regulation, social problem solving and conflict resolution skills), and develop effective school-based indicated interventions that can be used by school-based professional staff. Without these multi-level models of intervention, it is likely that at-risk middle school students will drift into a deviant peer group, where antisocial behavior, substance abuse, poor academic achievement, and rejection of mainstream social values, mores and institutions are reinforced. Moreover, these youth will lack the necessary social survival skills to succeed as in the school, peer group, and family social fields and are at increased for depression (Patterson et al., 1982). Consequently, a sole focus on early intervention efforts may fail to address the needs of youth.

Consistent with our second overarching aim, PRC Initiative 2 involves the pilot and feasibility testing of an extension of our K-5 integration of GBG+PATHS for grades 6-8. In PRC Initiative 3, we will develop and test the impact of another universal prevention program for middle school youth which aims to prevent depression using a classroom-based preventive intervention. As described above, the Patterson model suggests that depression may be a consequence of antisocial behavior, particularly in the middle school years. Thus, we are proposing to test alternative delivery models of the Structured Psychotherapy for Adolescents Responding to Chronic Stress (SPARCS) curriculum with BCPSS sixth graders. Finally, at the indicated level, PRC Initiative 4 seeks to develop and pilot test a developmental extension of Coping Power (Lochman & Wells, 1007) for grades 6-8. Coping Power was originally developed for aggressive/disruptive 4 and 5th graders and our current ACISR has been testing the feasibility of Coping Power in BCPSS to ensure it addressed contextual and cultural factors relevant to urban youth. In the current application, we propose to make developmental adaptations to the Coping Power Program and make other augmentations to increase generalizability and parental engagement during the middle school years.

Our multi-phase pilot and feasibility study process and infrastructure development efforts described in the Operations Core are designed to address many of the issues identified in our own work and that of others (Schoenwald & Hoagwood, 2001; Ringeisen et al., 2003) regarding successful implementation of evidence-based mental health preventive interventions in schools. Indeed, the Center’s initiatives are being designed and implemented with active support and participation of parents, children, teachers, and school administrators. Our dialogue with community partners around the design of these initiatives will be guided by these key issues. Indeed, support for training and supervision in the use of the Center’s interventions will be provided by a full-time BCPSS intervention coordinator, with funding from the proposed Center (see Operations Core).

PRINCIPAL RESEARCH CORE INITIATIVE 1: GBG+PATHS+PBIS+CCU Integration

1. SPECIFIC AIMS

Over the last 3.5 years, the JHU CPEI has supported the pilot and feasibility testing of the integration of 2 universal, elementary school, preventive interventions which have been shown in large scale, randomized controlled trials to have an immediate and beneficial impact on aggressive/disruptive and off-task behavior: the Good Behavior Game (GBG; Barrish et al., 1969; Brown, 1993; Dolan et al., 1993; Ialongo et al., 1999) and Promoting Alternative Thinking Strategies (PATHS; CPPRG, 1999; Greenberg et al., 1995). Our interest in integrating these two preventive interventions arose from their significant, but still modest effects as well as potential to create a
synergistic effect by combining effective and complimentary interventions (Brown, 2003; Dolan et al., 1993; Ialongo et al., 1999; CPPRG, 1999). The primary objective of our ongoing feasibility and acceptability study of GBG+PATHS is to determine whether teachers could learn and implement both the combined intervention without it resulting in high burden and poor implementation of both interventions. As summarized in the Preliminary Studies section, our feasibility and acceptability data suggest that teachers can successfully implement this combined model with quality implementation and acceptability. This pilot and feasibility study represented a first step toward the goal of a randomized trial and these findings led to a successful grant application to the IES that will compare the GBG+PATHS integration to the GBG alone and care as usual (“standard setting”). The trial will begin in the 2008-2009 school year, with 3 cohorts of 9 schools enrolling each year for a total of 27 schools. Within each cohort schools will be randomized to 1 of 3 conditions: 1) Standard Setting, 2) GBG Alone, and 3) GBG+PATHS. The trial will provide evidence of impact whether the combination of the GBG and PATHS yields a greater reduction in aggressive/disruptive and off-task behavior in grades K-5 than GBG alone or a standard setting (control) condition.

The research activities proposed in Initiative 1 of this application take advantage of the funded IES trial (PI: Nick Ialongo) by adding two additional arms to the IES trial to explore the impact of augmentations to further optimize implementation quality of the GBG+PATHS. Specifically, although our feasibility study has yielded reasonable levels of implementation fidelity and dosage of GBG and PATHS lessons, there is considerable room for improvement in both programs. Accordingly, a major aim of our this Research Core Initiative is to examine the impact of integrating PATHS and GBG with 2 other promising interventions Positive Behavioral Intervention Supports (PBIS) and the Classroom Checkup, which we hypothesize will increase GBG+PATHS implementation fidelity and frequency (amount/degree) and, in turn, GBG+PATHS’s impact on aggressive/disruptive behavior. Most theories of how effective practices are disseminated emphasize the importance of organizational context (Glisson, 2002; Hoagwood & Johnson, 2003; McDougal et al., 2000; Rogers, 1995). School-wide PBIS is one of the most widely implemented and successful, whole-school prevention strategy that alters the school environment by creating improved systems (e.g., discipline, reinforcement, and data management) and procedures (e.g., collection of office referral data, training, data-based decision-making) to promote change in student and teacher behaviors (Sugai & Horner 2002, 2006; Sugai et al., 2002). Using a similar positive behavior support framework, the Classroom Check-Up (CCU) was developed as a teacher coaching model that includes elements of motivational interviewing to enhance teacher motivation to improve their classroom management practices (Reinke, Lewis-Palmer, & Merrell, in press).

The aims of this Initiative require adding 3 arms to the IES funded trial of the GBG+PATHS combination in Years 2 & 3 of the IES trial and Years 1 & 2 of the proposed Center. These arms would allow us to obtain preliminary effect sizes as well as data on feasibility for an RO1 funded randomized control trial of the integration of the GBG+PATHS with PBIS and the CCU, separately and together. Accordingly, our specific aims are:

**Aim 1:** To estimate the magnitude of improvement in the impact of the GBG+PATHS on aggressive/disruptive and off-task behavior based on a comparison of the GBG+PATHS alone versus the GBG+PATHS with PBIS and the CCU, both separately and together.

**Aim 2:** To estimate the magnitude of improvement in implementation fidelity and frequency based on a comparison of the GBG+PATHS alone versus GBG+PATHS with PBIS and the CCU, both separately and together.

**Aim 3:** To estimate the magnitude of improvement in teacher perceptions of the effectiveness of the GBG and PATHS, their self-efficacy in implementing the GBG and PATHS, their attribution of student behavior change to the GBG and PATHS based on a comparison of the GBG+PATHS alone versus GBG+PATHS with PBIS and the CCU, both separately and together.

**Aim 4:** To explore whether any improvement in teacher implementation fidelity and frequency occur as a result of combining the GBG+PATHS with PBIS and the CCU, separately and together, is mediated by improvement in teacher perceptions of the effectiveness of the GBG and PATHS, their self-efficacy in implementing the GBG and PATHS, their attribution of student behavior.

**Initiative Team Members and Leadership.** Dr. Ialongo is Team Leader and will be joined by the BCPSS Intervention Coordinator, and Drs. Bradshaw, Domitrovich, Embry, Gittelsohn, Greenberg, Herman, and Reinke. Cost evaluations will be overseen by Dr. Slade and the statistical analyses will be overseen by Dr. Bandeen-Roche and assisted by the BCPSS Research Methodologist. See the Budget Justification for descriptions team members.

2. BACKGROUND & SIGNIFICANCE

2.1 Antisocial behavior and substance abuse are among the most common and serious behavioral health problems we presently face in the U.S. (CDC, 2006; 2007; FBI; 2007; SAMHSA, 2007). Their untoward impact and costs extend well beyond the individual manifesting these problems to the larger community within which these
individuals exist. Despite considerable evidence that aggressive/disruptive behavior as early as first grade predicts later antisocial behavior substance abuse, and low educational and occupational attainment, there have been few RCTs of potentially effective, universal preventive interventions aimed at decreasing aggressive/disruptive behavior in the elementary school years (Ialongo et al., 2006; Kellam et al., 1983; Schaeffer et al., 2003; 2006).

2.2 Overview of Johns Hopkins Prevention Intervention Research Center (JHU PIRC) Field Trials.

First Generation Trial. The JHU PIRC mounted a trial of 2 first grade, universal, preventive interventions in collaboration with the BCPSS. The 1st generation classroom-based, universal preventive intervention trial was fielded in 19 BCPSS schools with two cohorts of first graders in the 1985-86 and 1986-87. Two theory-based classroom interventions were evaluated; the Good Behavior Game (GBG; Barrish et al., 1969) was aimed at aggressive/disruptive and off-task behavior, whereas Mastery Learning (Bloom, 1976; 1982) targeted poor school achievement. The GBG is based on social learning principles and provides teachers with an efficient means of managing student aggressive/disruptive and off-task behaviors via reinforcement of the inhibition of these behaviors within a game-like context. Within five school clusters schools were randomized; one school received the Mastery Learning, one GBG intervention, and one school served as a control school to provide protection against within-school contamination. The results provided evidence that the proximal targets of poor achievement and aggressive/disruptive behavior were malleable, and that change in the proximal targets was associated with change in the distal outcomes in middle school and in early adulthood (Brown, 1993; Dolan et al., 1993; Kellam et al., 1994; 2008; Petras et al., 2008). The GBG resulted in significant—albeit modest—reductions relative to controls in aggressive/disruptive and off task behavior by the end of first grade, whereas Mastery Learning resulted in modest improvement in reading achievement (Brown, 1993; Dolan et al., 1993). More recently, Kellam et al. (2008) reported long-term benefits of the GBG with regard to reductions in antisocial behavior, violent crime, and substance abuse/dependence at ages 19-20, with the greatest impact among males and those with mild to moderate elevations in fall of first grade aggressive/disruptive behavior (Petras et al., 2008).

Second Generation JHU PIRC Field Trial. Our 2nd generation of JHU PIRC preventive interventions combined the GBG with and the academic program (e.g., Mastery Learning) with the aim of reducing early aggressive behavior and improving achievement (Ialongo, 1999). We also developed and fielded a universal, family-school partnership (FSP) intervention to contrast with the combination of GBG and an academic intervention. The proximal targets of the FSP intervention were poor achievement and aggressive/disruptive and off-task behavior. The 2nd generation JHU PIRC trial included 3 1st grade classrooms within each of 9 BCPSS elementary schools and a total sample size of 678 children and families. Teachers and children within each of the schools were randomly assigned to classrooms. In terms of the immediate effects of the interventions, the GBG+aademic intervention led to significantly fewer teacher-rated aggressive/disruptive behaviors than controls at the spring of Grades 1 and 2. The main effect of the FSP intervention proved significant in Grade 2, with FSP students showing lower levels of teacher-rated aggressive/disruptive behaviors than control children. No main effects were found for girls in the GBG+academic intervention or for FSP boys or girls. The impact on academic achievement was limited to boys and to Grade 1 for both intervention conditions. In Ialongo et al. (2001), we found that relative to controls, children assigned to the GBG+aademic intervention condition were significantly less likely to have a lifetime diagnosis of conduct disorder, have been suspended from school, and to have received, or been judged in need of, mental health services by teacher and/or parents. Moreover, both GBG+aademic intervention and FSP children were rated by teachers as exhibiting lower levels of conduct problems than standard setting or control children. FSP intervention girls were significantly less likely to have been suspended than control girls. Overall, consistent with Ialongo et al. (1999), the GBG+aademic intervention appeared to be the more effective in terms of reducing conduct problems and mental health service need and utilization in middle school. However, we did not see greater impact on aggressive-disruptive and off-task behavior from the GBG+aademic combination.

2.3 Combination of the GBG & PATHS. Given the combination of GBG with an academic intervention did not yield greater improvement in aggressive/disruptive behavior than those seen in the 1st generation trial of GBG alone, we pursued within our ACISR the integration of the GBG with a second and complementary, evidenced-based, universal preventive intervention: PATHS (CPPRG, 1999). The PATHS curriculum has been evaluated in a series of RCTs. Within the Fast Track study, which involved 198 intervention and 180 comparison classrooms from high-crime neighborhoods in four U.S. locations (CPPRG, 1999), the end of grade 1 data indicated that PATHS children had lower peer-rated scores on aggressive and hyperactive-disruptive behavior. At the end of grade 3, longitudinal findings comparing students who received 3 years of the PATHS curriculum with students in control schools and indicated that there were significantly lower rates of aggressive behavior, inattention, and poor academic behavior, and higher rates of prosocial behavior among the PATHS children. Peer sociometric reports indicated that PATHS students had significantly lower rates of peer-rated aggression and hyperactive/disruptive behaviors for boys and higher rates of prosocial behavior for both boys and girls (CPPRG, 2002). We expected an additive if not synergistic
effect as a result of combining the GBG and PATHS for the following reasons: 1) PATHS seeks to accomplish reductions in aggressive/disruptive behavior via teacher led instruction to facilitate emotion regulation, self-control and conflict resolution skills, whereas the GBG provides teachers with an efficient means of managing student aggressive/ off-task behavior via reinforcement of the inhibition of these behaviors within a game-like context (Greenberg et al., 1995). By increasing attention to task and reducing disruptive behavior, GBG may facilitate the acquisition of the emotion regulation, self-control, and conflict resolution skills taught in PATHS; 2) the social learning based GBG may increase the likelihood that students’ newly acquired skills would be appropriately prompted and reinforced by teachers. Consequently, the PATHS skills would be better learned and more frequently employed; 3) the increased teacher and child success, as a result of combining PATHS and GBG should minimize teacher and child discouragement and subsequent failure to comply with the intervention.

2.4 Hypothesized Mechanisms Underlying the Impact of the GBG+PATHS Interventions on Aggressive/Disruptive & Off-Task Behavior. Patterson et al.’s (1992) model of the development of antisocial behavior and academic failure provided the theoretical basis for JHU PIRC 1st and 2nd generation universal, classroom, and family-school partnership preventive interventions in the early elementary school years (Dolan et al., 1993; Ialongo et al., 2001). In keeping with Patterson’s (1992) model and Greenberg’s Affective-Behavior-Cognitive-Dynamic model (Greenberg & Kusche, 1996), both GBG and PATHS seek to reduce the early antecedent risk behaviors of aggressive/disruptive behavior and its distal correlates via changing teacher and student behavior. GBG provides teachers with an efficient way to inhibit aggressive/disruptive and off-task behavior in a “game” like context. PATHS trains teachers to provide explicit instruction in the development of emotion regulation, self-control, and conflict resolution skills in the context of curricular lessons. Accordingly, we hypothesize that the GBG+PATHS will reduce early aggressive/disruptive and off-task behavior and its adverse impact on academic achievement in the following manner: (1) The GBG+PATHS should improve the teacher’s ability to manage classroom behavior and facilitate socio-emotional development, which should then result in a reduction of early aggressive/disruptive and off-task behavior at the level of the child, classroom, and school; (2) as a result of the reduction in aggressive/disruptive and off-task behavior there should be fewer opportunities for modeling aggressive/disruptive behavior of their classmates; (3) children should then be at decreased risk of being rejected by parents/caregivers, teachers and peers; (4) moreover, parents should be more likely to monitor and supervise their children and engage in jointly reinforcing activities with them. (5) as a result, the children should be less likely to drift into a deviant peer group, where antisocial behavior, substance abuse, and poor academic achievement may be reinforced and mainstream norms and mores rejected (Brook et al., 1989; Hirschi, 1969; Jessor, 1978; Patterson et al., 1992); (6) Ultimately, the children would be less likely to fail in the classroom, family, and peer domains.

2.5. Factors Influencing Teacher Implementation of Evidence-Based Interventions. As a central goal if this project is to further enhance the implementation and effectiveness of the GBG+PATHS integration, it is important to consider the role of teacher, classroom, and school structure. Han and Weiss' model (2005) enhances our understanding of the process by which variables operating at the level of the teacher, classroom, and school affect implementation fidelity and sustainability. They conceptualize the implementation process as a “self-sustaining feedback loop”, with the training/consultation protocol playing the central role in that process. Our decision to examine the combination of GBG and PATHS with PBIS and the CCU reflects our belief that PBIS and the CCU target a number of the key factors and processes that can improve implementation fidelity presented in Han and Weiss (2005) and Domitrovich et al. (in press). A strong training and coaching model protocol should foster high initial levels of teacher perceived implementation efficacy and their attribution of improvements in student behavior to the intervention. This, in turn, should increase teacher motivation to implement the intervention with high fidelity. High levels of implementation fidelity should lead to improvement in student behavior and the teacher’s “experience of success” in implementation, which should then foster teacher self-efficacy and attributions of student improvement to the program, and in turn increase motivation to maintain high levels of implementation fidelity.

2.6 Rationale for Combining the GBG+PATHS with PBIS. As Han and Weiss (2005) noted in their summary of contextual factors involved in teacher program implementation, “Sustainability is likely to occur only in the context of institutionalization of systemic changes in attitudes, expectations, support mechanisms, and infrastructure” (p. 667). A multilevel school-wide discipline framework which has documented effects on promoting organizational climate and reducing problem behaviors across school settings may provide the optimal context for enhancing the implementation quality and outcomes achieved by GBG+PATHS. School-wide Positive Behavior Interventions and Supports (PBIS) is one such non-curricular, whole-school prevention model that promotes effective student behaviors through a data-informed behavioral systems approach (Sugai & Horner 2006). The three tiered public health model guides the PBIS prevention and intervention strategies for responding to problem behaviors by concentrating on the behavior and the environmental context in which the behavior occurs. PBIS offers a continuum
of services including a universal component whereby all students receive school-wide support marked by consistent rules and consequences, encouragement, and clear expectations across all school settings.

Over 6,500 U.S. schools have implemented PBIS (Bradley et al., 2005) and growing evidence suggests that successful implementation produces measurable and durable reductions in disruptive behaviors across school settings as well as lasting implementation of empirically supported practices by school personnel (see Barrett, Bradshaw & Lewis-Palmer, 2008; Bradshaw et al., in press; Bradshaw et al., under review). To date, the only longitudinal group randomized controlled trial of PBIS was conducted by Drs. Leaf and Bradshaw of the JHU CPEI in 37 elementary schools. They found that that two-thirds of the 21 elementary schools trained in PBIS exceeded the high implementation fidelity threshold within the first year of implementation, and the remaining one-third had met this criterion within the first 3 years (Bradshaw et al., 2008). All schools sustained high implementation quality throughout the duration of the four-year trial. Significant reductions in discipline referrals (ODRs), suspensions, and marginally significant improvements in school-level academic achievement were also observed (Bradshaw, Mitchell et al., under review). Similarly, non-randomized studies of PBIS have shown that schools that achieve a high level of implementation fidelity reduce ODRs by 20-60% (Taylor-Greene et al., 1997). Smith (2000) et al., under review). Similarly, non-randomized studies of PBIS have shown that schools that achieve a high level of implementation fidelity reduce ODRs by 20-60% (Taylor-Greene et al., 1997). Smith (2000) showed that reductions in ODRs achieved through PBIS led to reductions in problem behaviors in non-classroom settings. Systematic evaluations have demonstrated functional relationships between implementation of school-wide strategies and reduction in problem behaviors in settings such as playgrounds (Lewis et al., 2000) and common areas (Kartub et al., 2000). PBIS has also been shown to improve the organizational climate of schools which in turn may enhance the implementation quality of other preventive interventions. The NIMH-funded RCT of PBIS conducted by Drs. Leaf and Bradshaw indicated that PBIS was associated with significant and sustained improvements in multiple aspects of the schools’ organizational health, including collegial leadership, teacher affiliation, and academic emphasis (Bradshaw et al., in press; Bradshaw Koth et al., under review).

The organizational framework offered by PBIS may help encourage sustained implementation of other prevention initiatives, such as GBG and PATHS. Moreover, by improving school-wide climate and behavior management practices across school settings, PBIS may enhance the implementation quality and effects of classroom programs like GBG and PATHS. Furthermore, PBIS has been shown to increase the amount of instructional time available to teachers, which makes it more likely they can administer classroom behavioral and social interventions as intended (Scott & Barrett, 2004). By lowering the overall levels of disruptive behaviors in school, PBIS makes it more likely that teachers will have time to deliver GBG and PATHS so that students will be able to fully access the instruction.

PATHS+GBG also would complement and enhance the universal PBIS approach; all 3 preventive intervention models are based on many of the same principles (e.g., explicit instruction and reinforcement of behavior expectations, generalizing skills across settings), which increases the transfer of learning, but each model focuses on one of the three complementary domains (classroom on-task behavior, social-emotional development, orderly school structure and positive discipline). Although PBIS literature emphasizes the importance of social skill training, PBIS does not offer an explicit curriculum for teaching children social-emotional skills like those taught in the PATHS program. Similarly, GBG brings an added focus on classroom behavior management, which is lacking in the school-wide PBIS model. Classrooms are one of the most common settings for behavior referrals in schools (Irvin et al., 2006); therefore, by reducing classroom behaviors problem, GBG may maximize the effect of PBIS and lower the overall level of student disruptions. Therefore, the combination of PATHS, GBG, and PBIS provides the potential for a synergistic effect, both directly on behavior problems and indirectly through enhanced program implementation.

2.7 Rationale for Combining the GBG+PATHS+PBIS with the CCU. Our efforts to maximize implementation fidelity and frequency in our current JHU CPEI supported pilot and feasibility studies of the GBG+PATHS combination were shaped by the models of implementation fidelity offered by Han & Weiss (2005) and Domitrovich et al. (in press). More specifically, our GBG+PATHS training and coaching protocols developed during the initial feasibility trial of GBG and PATHS included 1) A discussion of the theoretical principles upon which the interventions are based, along with the evidence of their efficacy among economically-disadvantaged, urban, ethnic minority youth; 2) Intervention manuals provided to teachers in hard as well as electronic versions; 3) Three full days of training provided by the intervention developers and their staff (including modeling of the use of the GBG and PATHS intervention components by the trainers, viewing of videotapes of teachers within the BCPSS implementing GBG and the PATHS lessons, role plays and guided practice in the use of the GBG and PATHS, and teacher panels consisting of teachers who have successfully implemented the intervention and who share their successes with teachers in training; 4) On-going consultation provided to teachers throughout the school year by a coach; and 5) Coaches observed teacher implementation of each intervention and provided them with constructive feedback. Despite providing multiple forms of support to teachers implementing GBG and PATHS, a significant proportion of teachers continued to exhibit low levels of implementation fidelity and frequency/amount. Finding methods to assist low implementers to improve their fidelity is a critical need for school-wide adoption of effective practices. While we
expect that embedding GBG and PATHS within PBIS will improve teacher implementation, it is anticipated that some teachers will continue to struggle with implementing GBG and PATHS. Those teachers who struggle despite the ongoing support and school-wide organizational framework of PBIS would likely benefit from a more intensive and more personalized intervention directed at improving implementation integrity.

One method proven to be especially helpful in improving adherence is motivational interviewing (MI; Miller & Rollnick, 2002). Although initially developed to address motivation of substance users, MI principles have since been extended to effectively promote motivation and adherence to a variety of populations and problem areas, including adolescent risky behaviors, eating disorders, and families of children with disruptive behavior problems. Whereas most of these applications have focused on improving compliance among patient populations, recent applications have focused on using MI principles to improve implementation practices of providers. The Classroom Check-Up (CCU) is a teacher coaching model based on MI to enhance teacher motivation to improve their classroom behavior management practices (Reinke, Lewis-Palmer, & Merrell, in press). Some specific motivational enhancement strategies utilized by the CCU include personalized feedback to teachers on classroom behaviors, encouraging personal responsibility for decision making while offering direct advice if solicited, development of a menu of options for interventions, and supporting teacher self-efficacy by identifying existing strengths and times when teachers have successfully changed classroom behaviors in the past (see Miller & Rollnick, 2002) – all noted as being critical to high implementation quality (Domitrovich et al., in press). Reinke, Lewis-Palmer, and Merrell (in press) reported the development of the CCU as a classwide coaching model to address the need for classroom level support while minimizing treatment integrity problems common to school-based consultation. They evaluated the effects of the CCU and Visual Performance Feedback (VPF) on teacher and student behavior in a multiple baseline design across four classrooms in four elementary schools. The CCU plus VPF increased teacher implementation of classroom management strategies, including increased use of praise, use of behavior specific praise, and decreased use of reprimands. Further, these changes in teacher behavior corresponded to decreases in classroom disruptive behavior and were maintained over time. The results are encouraging because they suggest that systematic consultation at the classroom level as a universal prevention strategy can create meaningful teacher and student behavior change. Additionally, Reinke, Lewis-Palmer, and Martin (2007) demonstrated the effects of the CCU plus VPF as a selective preventive intervention. They evaluated the effects of the model on teacher use of behavior-specific praise using a multiple baseline design with three general education elementary teachers and six targeted students with classroom behavior problems. The results indicated that the combination of CCU and VPF resulted in an increase in behavior-specific praise for students across all teachers. Additionally, teachers increased their use of behavior-specific praise with classroom peers suggesting the CCU has collateral effects. Finally, Mesa, Lewis-Palmer, and Reinke (2005) reported that the teacher coaching model with the VPF resulted in a significant increase in teacher use of specific praise which in turn led to reductions in student disruptive behaviors on a classwide level. All three studies relied on rigorous evaluation procedures including real-time data collection of key study variables. Also, across all three studies, teachers rated the intervention as very important, effective, unobtrusive, and practical (e.g., requiring minimal time, resources, and effort to implement). Collectively, these studies indicate the CCU model is a feasible, acceptable, and effective method for improving implementation of evidence-based practices.

The CCU may be an optimal support system for teachers who experience difficulties implementing GBG+PATHS with high fidelity. Currently, coaches monitor teacher implementation of GBG+PATHS using an implementation rubric which provides an objective measure of teacher implementation across core components. Each teacher is provided a score based on observations conducted by the consultant in the classroom, ranging from 0 (i.e., low to no implementation) to 4 (i.e., high implementation with consistent use of effective practices). Based on these assessments teachers in need of additional supports can be readily identified. Teachers having trouble implementing GBG+PATHS would then be provided the CCU. Those teachers who continue to struggle following the CCU with be provided additional feedback in the form of video performance feedback. Performance feedback, although time intensive, is among the most promising methods for increasing the implementation of evidence-based instructional practices (Jones, Wickstrom, & Friman, 1997; Noell et al., 1997; 2005; Reinke et al., 2007). For instance, Reinke et al. (2007) found that performance feedback increased teacher use of effective classroom management practices above and beyond initial training and consultation. In summary, we are proposing to provide supports to teachers implementing GBG+PATHS in a multi-tiered, public health approach (Mrazek & Haggerty, 1994). At the universal level, all teachers would receive standard training and ongoing supervision and support. Teachers who have difficulty implementing with high fidelity (up to 20%) would receive indicated support in the form of a CCU. We expect a small % of teachers would continue to be low implementers even with CCU support. These remaining teachers would receive intensive individualized support in the form of video performance feedback. In this manner, we would maximize resources by providing the most intensive supports only for those teachers who need it.
3. PRELIMINARY STUDIES

3.1 Overview of the Current ACISR Supported Intervention Development, Feasibility & Acceptability Work. Our ACISR supported GBG+PATHS intervention team (Drs. Embry, Greenberg, Domitrovich, & Ialongo) has spent the last 3.5 years developing and refining the GBG+PATHS combination, along with an implementation support system that would maximize quality and effectiveness. This process began when the developers trained in each other’s intervention and spent time observing the program as it was being used by teachers in community settings. The first step in the intervention development process was to conceptually integrate the two interventions. Great care was taken to integrate the two programs while remaining consistent with each program’s theoretical model. This was then translated into the rationale for lessons, activities, and practices. The second step involved streamlining the GBG+PATHS combination into a single intervention that was feasible for teachers to use in the classroom. We revised the original program materials so they no longer referred to the original interventions and so they would be executed simultaneously without too much burden on teachers. A standardized curriculum manual and set of materials (e.g., puppets, books, posters) were created that could be duplicated each year as the program expanded. Consistent with the goal of communicating to teachers and administrators that the GBG+PATHS combination was in fact one intervention, we named the combined intervention “PATHS to PAX”. However, for simplicity’s sake, we will continue to use the term the GBG+PATHS combination throughout this application.

The third step in the program development was to create an effective training model that prepared teachers to use the combined intervention. The developers spent a significant amount of time integrating their existing presentations around the rationale for the combined intervention. Areas where the training materials from each intervention overlapped were combined and group exercises were created to supplement the lectures. This initial version of the training model was then implemented in 6 BCPSS K-5 elementary schools in the 2005-06 school year (described in more detail below). Following this initial implementation and with feedback from teachers in the form of focus groups, individual interviews, and anonymous questionnaires, a second generation of the training model was developed. Videotaped footage taken of BCPSS teachers successfully using the various GBG and PATHS elements and practices and teacher testimonials were incorporated into the training model. The combined GBG+PATHS curriculum materials were reorganized based on teacher feedback. All of these materials were then made available on the BCPSS website, so participating teachers could access them following the training for further study at their convenience. In general, all these efforts were aimed at developing a high quality training model and a set of materials that teachers would find appealing and easy to use and access. We then designed a system to monitor implementation that was linked to professional development. Several tools were developed to promote high quality implementation by teachers including a “recipe for success” and a GBG+PATHS feedback form, which were based on the definitions of quality that underlie the ratings conducted by coaches. A consultation or “coaching” model was developed that formalized the use of these monitoring and feedback forms and set benchmarks for implementation quality that could be used to determine the frequency of support provided.

3.2 Evidence of Feasibility & Acceptability. The primary objective of our ACISR supported feasibility and acceptability studies of the GBG+PATHS combination was to determine whether asking teachers to learn and implement both GBG and PATHS at the same time would prove overly burdensome and result in poor implementation of both interventions. Six K-5 BCPSS elementary schools participated in the GBG+PATHS pilot. The student populations in these 6 schools are predominantly African-American (84% or higher) and economically disadvantaged (90% or higher free lunch eligibility). Seventy-three teachers from these 6 schools participated in a 3-day training in the GBG+PATHS during the summer of 2006. The training reflected a single underlying theme of improving student behavior and social emotional development via both the GBG and PATHS lessons, however, approximately 1 day was dedicated to the GBG and 2 days to PATHS. Six of the teachers elected not to implement either the GBG or PATHS, thus data are only available for 67 teachers. The coaches conducted observations of teachers’ fidelity of implementation at 3-time points over the 2006-07 school year. Immediately following the initial training in GBG+PATHS, teachers completed an anonymous evaluation of the quality of the training and to report on their perceptions of the GBG+PATHS combination (e.g., perceived need for the intervention, perceived ease of implementation). Teachers also completed an end of year evaluation of GBG+PATHS.

Teacher Perception of Intervention Attributes Scale-Prior to Implementation. At the conclusion of the training, participating teachers completed the Teacher Perceptions of Intervention Attributes Pre-Implementation scale (TPIA-PRI), which we developed as part of ACISR supported pilot and feasibility efforts. The TPIA-PRI consists of questions based on the factors identified in Han & Weiss’ model (2005) of teacher implementation of evidence based practices, including perceived need, developmental and cultural appropriateness, ease of implementation, and the value of implementation relative to the costs in terms of time, resources, and effort. The overwhelming majority of teachers perceived a need for the PATHS lessons and the GBG (91.8%, “a lot” to “a great deal”), believed both (GBG, 84.8%, PATHS, 84.8%; “a lot” to “a great deal”) would be useful, were highly confident
that they could implement both (GBG, 78.9%, and PATHS, 77.5%; “a lot” to “a great deal”) and felt the resources necessary to implement both were justified (GBG, 84.8%, and PATHS, 84.8%; “a lot” to “a great deal”). Moreover, both the GBG and PATHS lessons were seen as developmentally and culturally appropriate and slightly over 80% of teachers responded “a lot” or “great deal” as to how likely they were to implement the GBG+PATHS lessons.

**Teacher Perception of Intervention Attributes Scale—Post Implementation: Summary of End of Year Evaluation Findings.** Based on the TPIA-PRI scale and consistent with the Han & Weiss (2005) model, we developed a multi-dimensional scale administered following intervention implementation. The TPIA-PSTI assesses many of the same domains included in the pre-Implementation version, but expands the number of questions as teachers are better able to report on the elements of PATHS+GBG after implementation. The TPIA-PSTI was administered at the end of the 2006-07 school year. Over 75% of the teachers reported using the GBG at least 2-3 times per week and about 25% reported daily use of the GBG (2-3 times per day, every day). Just over 2/3 of teachers reported implementing PATHS (1-2 lessons per week) on a daily basis. Nearly 80% of teachers reported the GBG “somewhat easy” to “very easy” to fit into their schedules, whereas under 70% reported it “somewhat easy” to “very easy” to implement the GBG+PATHS lessons.

Coaches’ implementation fidelity was rated approximately 30-minutes in length, during which they made global ratings of the quality of implementation of the GBG and PATHS elements. Data from the coaches’ final (mid-May) ratings indicate that over 73% of the teachers were average to highly skilled in implementing GBG, with only about 11% rated as poor. Nearly 75% of the teachers were rated as average to highly skilled in terms of teaching the PATHS lessons and practices, whereas 60% of teachers were rated as “skilled” to “highly skilled” in the modeling and generalization of PATHS concepts.

3.3 Summary of Preliminary Research. Most teachers perceived the GBG and PATHS “somewhat easy” to “very easy” to implement and to fit into their normal routine. A substantial majority of teachers reported using the PATHS lessons and practices frequently and playing the GBG at least 2-3 times a week. The coaches’ implementation ratings suggest that many teachers are implementing the GBG+PATHS at a skilled to highly skilled level. In comparing these data on implementation with those from our previous GBG and PATHS trials, the level of implementation is at least equal to or better than that found in our previous research (CPRGR, 1999; Dolan et al., 1993). These findings suggest that teachers can implement both the GBG and PATHS at the same time with reasonable quality. However, as noted above, there is still considerable room for improvement in implementation frequency and fidelity, given over 10% of the teachers were rated by our GBG+PATHS coaches as poor when it came to their implementation of the basic GBG components and over 25% were rated as less than skilled implementers of PATHS. Moreover, only about 40% of teachers reported implementing the GBG the recommended 2-3 times per days and administering the PATHS lessons twice a week.

4. METHODS

4.1 Overview of the Research Design. The IES funded trial will utilize a school-based group-randomized trial (GRT) to evaluate whether the GBG+PATHS yields a greater reduction in aggressive/disruptive and off-task behavior in grades K-5 than the GBG alone or a standard setting (control) condition. A GRT is required given randomization occurs at the level of the school and not the individual student (Murray, 1998). The aims of this proposed PRC initiative require adding 3 arms to the IES funded trial design in Years 2 and 3 of the IES trial and Years 1 & 2 of the proposed Center. These arms would allow us to obtain preliminary effect sizes for an RO1 funded randomized control trial of the integration of the GBG+PATHS with PBIS and the CCU, separately and together. More specifically, we will seek to estimate the magnitude of improvement in GBG and PATHS implementation fidelity and frequency based on a comparison of the GBG+PATHS alone versus GBG+PATHS with PBIS and the CCU, separately and together. In addition, we will estimate the magnitude of improvement in the impact of the GBG+PATHS on aggressive/disruptive and off-task behavior based on a comparison of the GBG+PATHS alone versus the GBG+PATHS with PBIS and the CCU, separately and together.

**Specifics of the IES Design.** The IES trial features an extended nested-cohort design in which identifiable social groups are randomized to each condition and members of those groups are measured on 3 or more occasions over
time to assess the impact of the interventions (Murray, 1998). The IES design calls for 3 study conditions: Standard Setting (Control), versus GBG alone, versus GBG+PATHS. Nine elementary schools will be randomized to each condition for a total of 27 schools. The IES trial includes 9 schools in the 1st year, 9 in the 2nd year, and 9 in the 3rd year. Each set, or cohort, of 9 will have 3 schools randomized to each of the 3 conditions. In each school, we estimate that we will assess 50-56 students in each of 6 grades, K-5, for a total of 300-336 students per school. This will provide 3 follow-ups for the 1st set, or cohort, of 9 schools, 2 for the 2nd, and 1 for the 3rd.

4.2. Specifics of the Proposed CPEI Initiative 1 Design. We are proposing to add 3 arms to the IES design, which translates into 3 additional schools in Years 2 (Cohort 2) and 3 (Cohort 3) of the IES design, respectively, and Years 1 & 2 of the proposed ACISR. One of the additional schools each year will receive GBG+PATHS+PBIS. One will receive GBG+PATHS+CCU and one will receive the GBG+PATHS+PBIS+CCU. Table 1 in Appendix PRC1 summarizes the design for the IES trial and this proposed CPEI Initiative.

4.3 Timing of the Assessments. Aggressive/disruptive and off-task behavior will be assessed at pretest and posttest using direct observations and teacher ratings. Other endpoints including grades, number of suspensions, office referrals for disciplinary action, and referrals for and/or use of special education services will be collected annually from archival records maintained by the schools and directly from teachers.

4.4 Randomization. Each set, or cohort, of schools will be rank ordered on the mean aggressive/disruptive and off-task behavior score based on the independent observations of student behavior carried out at pretest in the fall of the school year. Schools adjacent in rank will be paired. Schools will then be randomized to the interventions conditions from within matched pairs (Donner & Klar, 2000; Murray, 1998)

4.5 Hypotheses to Be Tested. Given space limitations, we provide only the overarching hypotheses to be tested. Section 2.3 of this Initiative provides greater detail on the hypothesized mechanisms of intervention impact.

Hypothesis 1: The combinations of the GBG+PATHS with PBIS and CCU, separately and together, will yield a higher level of implementation fidelity and frequency/amount than the GBG+PATHS alone condition. We also hypothesize that the GBG+PATHS+PBIS+CCU condition will result in the highest level of GBG+PATHS implementation fidelity and frequency/amount relative to GBG+PATHS alone or in combination with PBIS or the CCU, separately.

Hypothesis 2: The combinations of the GBG+PATHS with PBIS and CCU, separately and together, will yield a higher reduction in aggressive/disruptive and off-task behavior than the GBG+PATHS alone condition. We also hypothesize that the GBG+PATHS+PBIS+CCU condition will result in the highest reduction in aggressive/disruptive behavior relative to GBG+PATHS alone or in combination with PBIS or the CCU, separately.

Hypothesis 3: In contrast to the GBG Alone and the GBG+PATHS, the combinations of the GBG+PATHS with PBIS and CCU, separately and together, will yield a great level of improvement in teacher perceptions of the effectiveness of the GBG and PATHS, their self-efficacy in implementing the GBG and PATHS, and their attribution of student behavior change.

Hypothesis 4: We will find evidence that suggests the hypothesized improvement in teacher implementation fidelity and frequency as a result of combining the GBG+PATHS with PBIS and the CCU, separately and together, is mediated by improvement in teacher perceptions of the effectiveness of the GBG and PATHS, their self-efficacy in implementing the GBG and PATHS, their attribution of student behavior.

4.6 Description of the Interventions

Good Behavior Game. The GBG originally developed by Barrish et al. (1969) allows teachers to utilize social learning principles within a team-based, game like context to reduce aggressive/disruptive and off-task behavior and, consequently, facilitate academic instruction. The “PAX” version of GBG represents Dr. Embry’s and colleagues’ efforts to improve the effectiveness of the original GBG and to make it ready for wide scale dissemination (Embry et al., 2003). Like the original GBG, the PAX GBG is essentially a group-based token economy, where the groups or “teams” are reinforced for their collective success in inhibiting inappropriate behavior. The team based nature of the game allows teachers to take advantage of positive peer pressure in managing student behavior at the individual and the classroom level. The students are rewarded for displaying self-control and emotion regulation and not attending to the misbehavior of others. The rewards for winning the game are usually non-material and include activities such as listening to music, getting to sit on soft cushions, or blowing bubbles.

Promoting Alternative Thinking Strategies (PATHS). PATHS is based on the Affective-Behavioral-Cognitive-Dynamic model of development (Greenberg & Kusche, 1996; Greenberg et al., 1990), which places primary importance on the developmental integration of affect (and emotion language), behavior, and cognitive understanding as they relate to social and emotional competence. PATHS is designed to improve skills in four domains: 1) prosocial friendship skills, 2) emotional understanding and emotional expression skills, 3) self-control
implement the intervention on their own and giving them constructive feedback on their implementation. Our plan is for implementing the intervention, modeling the intervention components for them, and then observing the teachers day to complete the GBG training component, along with 2 subsequent Saturday training days for the GBG+PATHS GBG and 2 days PATHS). The IES trial calls for taking advantage of the BCPSS October professional development/ emotion regulation (e.g., the capacity to inhibit impulsive behavior and organize goal-directed activity), and 4) problem solving skills which, in turn, are expected to improve problem behavior and social-emotional skills. About 40% of the lessons focus on skills related to understanding and communicating emotions; 30% focus on skills related to the increase of positive social behavior (e.g., social participation, prosocial behavior, communication skills). Additional, lessons address making/sustaining friendships, using good manners, taking turns and sharing in games, expressing one’s viewpoint, listening to others, social problem solving, and self-control.

**Positive Behavioral Intervention Supports (PBIS).** School-wide PBIS is a non-curricular universal prevention strategy that aims to alter the school environment by creating improved systems (e.g., discipline, reinforcement, and data management) and procedures (e.g. office referral, reinforcement, training, leadership) that promote positive change in staff and student behaviors. This whole-school strategy aims to prevent disruptive behavior and enhance the school’s organizational climate by creating and sustaining primary (school-wide), secondary (classroom), and tertiary (individual) systems of support. The three-tiered prevention model follows a public health approach, whereby two levels of targeted and selected programs are implemented to complement the universal school-wide components of the model (for a review, see Sugai & Horner, 2006; Suga et al., 2000). The U.S. Department of Education has funded the Technical Assistance Center on PBIS, co-directed by Drs. George Sugai and Robert Horner, to support the nation-wide PBIS effort by providing technical assistance to states like Maryland.

**Classroom Check-up (CCU).** The CCU is a brief intervention model derived from motivational interviewing, an empirically-driven theory of behavior change (Miller & Rollnick, 2002), and developed to address the need for teacher support in implementing effective practices in the classroom while minimizing fidelity problems common to school-based interventions. The CCU is an assessment-based strategy involving a comprehensive assessment of the teacher's classroom behaviors, followed by feedback to the teacher. This check-up strategy has been successfully used previously with problem drinkers (the Drinker Check-Up; Miller & Sovereign, 1989; Schippers, Brokken & Otten, 1994) and with families of children with problem behaviors (the Family Check-Up; Connell, Dishion, Yasui, & Kavanagh, 2007; Dishion & Kavanaugh, 2003; Shaw et al., 2006). The CCU builds on existing school-based coaching and consultation models by emphasizing class-wide change and motivational enhancement strategies. Specific motivational enhancement strategies include personalized feedback to teachers on classroom behaviors, encouraging personal responsibility for decision making while offering direct advice if solicited, development of a menu of options for improving fidelity, and supporting teacher self-efficacy by identifying existing strengths and times when teachers have successfully changed classroom behaviors in the past (Miller & Rollnick, 2002). The CCU is a process that occurs in a series of steps: (1) The coach assesses the classroom with a focus on teacher implementation quality; coaches will conduct a brief interview with classroom teacher to build rapport and identify areas of teachers concern and they will compile data from classroom observations of implementation quality of GBG+PATHS. (2) Teachers are provided with feedback on current strengths and weaknesses in their implementation quality. Feedback is shared objectively using forms that illustrate points by using the stop light colors (red, yellow, green). Areas of strength (or areas of high implementation) fall into green areas on a visual bar graph and areas of weakness or low implementation fall into red areas on a visual bar graph. (3) Following feedback the coach and teacher develop a menu of potential strategies for increasing effective practices and implementation quality. (4) The teacher and coach collaboratively identify from the menu the specific strategies that will be implemented. (5) The teacher self-monitors implementation of the strategies and intervention. Following the CCU teachers will be monitored and provided additional support, if needed, to further increase implementation in the form of performance feedback. In this study, teachers who are identified for performance feedback will receive this feedback in the form of video performance feedback. Coaches will videotape teacher implementation of GBG+PATHS, then meet with the teacher during a scheduled time to review the tape together and discuss areas of strength and weakness in implementation quality. A subset of classroom teachers in the GBG+PATHS+CCU and GBG+PATHS+PBIS+CCU schools identified as poor implementers will receive the CCU. Coaches will identify the teachers from their regular observation of implementation quality.

**4.7 Overview of Intervention Training & Consultation Schedule & Protocols.** With the exception of the CCU, training will begin in the last week of October for all intervention conditions following the pre-test, or baseline assessments, and the random assignment of schools to intervention conditions. Separate trainings will be held for each condition.

**GBG+PATHS.** As described above, the combined GBG+PATHS training will occur over 3 days (roughly 1 day GBG and 2 days PATHS). The IES trial calls for taking advantage of the BCPSS October professional development day to complete the GBG training component, along with 2 subsequent Saturday training days for the GBG+PATHS condition. The GBG+PATHS coaching model calls for the coach to assist each teacher in setting up their classroom for implementing the intervention, modeling the intervention components for them, and then observing the teachers implement the intervention on their own and giving them constructive feedback on their implementation. Our plan is
to complete this task in the week subsequent to training. Following this initial phase of the coaching model, the intervention coach will be available onsite in each of the schools on a bi-weekly basis throughout the initial year of training and coaching in the interventions. Between onsite visits, the coach will be available via e-mail and by phone on a more frequent basis as needed. The coach will continue to a) model the use of GBG and PATHS, b) provide in classroom guided feedback, and c) provide face-to-face, on-line, and telephone consultation.

**PBIS.** The schools randomly assigned to receive PBIS training will form internal PBIS teams comprised of 7 members (e.g., staff, teachers, administrators), which will attend a two-day initial training led by Ms. Susan Barrett and Dr. Bradshaw. The first day of the training reviews the 7 critical elements of school-wide PBIS (e.g., *Expectations Defined, Behavioral Expectations Taught, System for Responding to Behavioral Violations*). The second day focuses on action planning. Research by Barrett et al. (2008) indicates that the Maryland training procedures are effective at producing sustainable changes in the school and are effective at producing the intended outcomes. Ongoing support for the schools is provided through a PBIS behavior support coach, a PBIS coordinator, and the Maryland State PBIS Leadership Team. To ensure consistently high levels of implementation, PBIS teams will attend 2 single-day “booster” training events during the first year of the trial, then attend the 2-day annual PBIS summer booster training session which is led by BCPSS. Additional supports and training are provided to the PBIS coaches by the State PBIS Team at 4 annual coaches’ training events.

**CCU.** Coaches will be trained and supervised to implement the CCU by Drs. Reinke and Herman in mid-September. The 2-day training for coaches on the CCU will include 1) a discussion of the theoretical basis for the intervention and the evidence base supporting its use, 2) modeling of the use of intervention components by the trainers, 3) role plays and guided practice in the use of the intervention components, and 4) personalized feedback to coaches on the quality of CCU implementation. After the training, coaches will receive ongoing supervision from Drs. Reinke and Herman, including review and feedback of video-taped CCU sessions between coaches and teachers to ensure procedural integrity and quality. Bi-weekly phone conference calls and bi-annual onsite consultation between the coaching staff and Drs. Reinke and Herman also will occur during the Initiative.

### 4.8 Measures of Implementation Quality

**GBG+PATHS Fidelity: Teacher Reports.** In terms of GBG, teachers will report the number of games played each day, the length of the games in minutes, and the number of times each team won a game. Similarly, teachers will report on the number of PATHS lessons taught that day and the percentage of each lesson completed. Teachers will enter the data into the INSPIRE web-based, electronic system developed with support from our previous ACISR and described in the Operations Core. Teachers will continue to report on their implementation of the interventions beyond the initial year of their training and coaching.

**GBG+PATHS Fidelity: Coach Observations.** The GBG+PATHS coaches will complete 8 observations over the initial school year of teacher implementation of the GBG and PATHS lessons. GBG teachers will be asked to play the “game” during these observations, whereas PATHS teachers will be asked to do a PATHS lesson. For the GBG+PATHS combination, teachers will be asked to do both. That is, play the GBG as well as do a PATHS lesson during their observation period. For the GBG, the coach will use a 15-item implementation observation scale developed during our ACISR pilot and feasibility studies, whereas for the GBG+PATHS, the scale will include 22-items to reflect the need for observation of PATHS implementation as well as the GBG). In both cases, about a 1/3 of the items assess more general aspects of the teacher’s classroom management skills; these items include teacher interpersonal style (e.g., teacher creates a positive and responsive atmosphere), level of punitive discipline (e.g., does not use punitive or shaming techniques), and teacher management skills (e.g., teacher provides clear structure, expectations and routines and consistent discipline). The remaining items are based on the “recipe” given to teachers for playing the GBG and doing a PATHS lessons. The recipe contains each of the steps necessary to conduct a successful game or lesson. All the items are rated by the coach on a 5-point scale, with 1 indicating that none of the identified characteristics or interventions elements were observed or evident and 5 meaning the highest degree of fidelity. Our ACISR pilot and feasibility efforts indicated that high interrater agreement among the coaches, with the ICC > .85 for all but one item (choice of an appropriate activity for students to complete during the playing of the GBG, which is currently being refined). We also examined the correlations between the overall fidelity score (aggregated across all 22-items) and teacher reports on the Teacher Perception of Intervention Attributes Post-Implementation Scale (TPIA-PSTI) described above. The correlations between the overall score and teacher reports of impact on classroom behavior and child socioemotional development, ease of use, and fit with schedule and teaching philosophy ranged from .81 to .87.

**PBIS Fidelity.** The developers of PBIS created the School-wide Evaluation Tool (SET; Sugai, Lewis-Palmer, Todd, & Horner, 2001) as a measure of the degree to which schools are implementing the key features of school-wide PBIS (Horner et al., 2004). The SET is completed annually by a trained external observer who assesses the following 7 key features of school-wide PBIS: *Expectations Defined; Behavioral Expectations Taught; System for
Rewarding Behavioral Expectations; System for Responding to Behavioral Violations; Monitoring & Evaluation; Management; and District-Level Support. It is posited that the intended benefits of PBIS occur when PBIS is implemented with at least 80% fidelity. Schools are expected to continue to experience improvements or stabilize once this level of implementation has been reached. Horner et al. (2004) found the SET to have strong psychometric properties, including a high internally consistency, interobserver reliability, and strong test-retest reliability.

Administration of the SET. The SET is conducted by a trained assessor on a single day and lasts approximately 5 hours, during which the assessor determines the degree to which a school has each of the model's 7 critical features in place by reviewing written materials and established discipline procedures and noting visual displays of the three to five expected behaviors posted throughout the school. SET assessors conduct brief interviews about school procedures, policies, and standards for positive behavior and rule infractions with administrators, students, and school staff. SET assessors are primarily master's and doctorate level professionals who have extensive experience working in educational settings. Dr. Bradshaw and Ms. Barrett have trained over 60 SET assessors in Maryland, of which 25 assessors conducted SETs in Drs. Leaf and Bradshaw’s randomized controlled trials of PBIS (Bradshaw et al., 2008). An initial SET training and an annual recalibration training session will be held to ensure high inter-rater reliability throughout the duration of the trial. Because PBIS is the confluence of several effective behavior management and organizational practices, it is important to monitor the level of PBIS in schools which have not been formally trained in PBIS (Bradshaw et al., 2008). Consequently, the SET will be administered in schools across all arms of the PATHS+GBG+PBIS+CCU trial. SETs will be conducted by the trained assessor (who is unaware of the schools’ implementation or training status) at baseline, and in the spring of the school year to monitor the implementation quality of school-wide PBIS, across all schools.

4.9 Outcome Measures. Aggressive/disruptive behavior and time off task will be assessed at pretest and posttest using direct observations (Fast Track Classroom Observation System, CPPRG, 1999; Sutherland et al., 2002), teacher ratings (Teacher Observation of Classroom Adaptation-Revised, TOCA-R, Werthamer-Larsson et al., 1991), and school records. A description of the key outcome measures and a table summarizing the timing of the administration of the assessment is provided in Appendix PRC1.

4.10 Descriptions & Schedule of Administration of Measures of Variation in Teacher Implementation Level & Fidelity. TP1A-PRE will be administered immediately after training. The TP1A-PST will be administered in mid-December and March of the initial implementation year, which allow for an assessment of teacher perceptions of the efficacy of the interventions - a central factor in Han and Weiss' model (2005) of factors influencing teacher implementation of evidence-based interventions in school settings.

5. DATA ANALYSIS

5.1 Primary Outcomes Analysis. The primary aim of the IES trial is to determine whether the interventions are differentially effective compared to each other and to the control condition in terms of aggressive/disruptive and off-task behavior over the course of a single school year. This is also consistent with Aim 2 of the proposed initiative as well. Separate analyses will be carried out for each method of assessing outcomes. The primary analyses in both the IES trial and this proposed PRC initiative will use the pretest and posttest outcome measures for each grade and each school, respectively. Pooling across grades, we will use a mixed-model ANCOVA to compare the three conditions on the primary outcome measures as assessed in the spring with regression adjustment for fall baseline levels of the outcome measures. Condition and the fall aggressive/disruptive and off-task behavior scores will be included as fixed effects while school and child will be included as nested random effects. The null hypothesis of no intervention effect is assessed by testing the variation among the conditions against the average variation among schools within conditions (Murray, 1998).

5.2 Analysis of PBIS and CCU Impact on Teacher Implementation & the Putative Factors Influencing Implementation. The primary analytic tool to assess the impact of PBIS and the CCU on implementation fidelity and frequency/amount and the putative factors influencing implementation will be random coefficient growth modeling and its reformulation as a latent growth model (LGM) as encompassed in Mplus 5.1 (Muthen & Muthen, 1997-2007). More specifically, using LGM we plan to fit models of the growth of the frequency and fidelity, respectively, of teacher implementation of the PATHS and the GBG interventions. We will then regress the latent growth factors (initial status and slope, including linear and quadratic slopes) for the implementation and factors influencing implementation on intervention status, which will be dummy coded to reflect the comparisons of interest: GBG+PATHS alone versus GBG+PATHS+PBIS, GBG+PATHS+CCU, GBG+PATHS+PBIS+CCU. Separate LGM models will be carried out for the interventions and the types of implementation data (coaches’ ratings and teacher report of the frequency of use) and putative factors influencing implementation. To explore whether the impact of PBIS and the CCU on implementation is mediated via their impact on the putative factors influencing teacher implementation, we will carry out a series of sequential process LGM models as described in Muthen and Curran (1997). In a sequential process model, one fits two of more separate growth processes and then regresses the
slopes and intercepts of the later processes on the slopes and intercepts of previous processes along with covariates measured prior to the initial time point for each process. The use of sequential growth processes allows us to include in our LGM models the multiple measurements of the factors influencing implementation. Thus, we can account for the effects of change in these factors over time on the growth of implementation. Also see the Principal Methods Core for an overview of estimating intervention effects in the presence of variation in implementation and economic analyses, which will be undertaken in conjunction with Drs. Bandee-Roche and Slade.

1. PRINCIPAL RESEARCH CORE INITIATIVE 2: Middle School PATHS + GBG

1. SPECIFIC AIDS

Prevention initiatives face a number of significant challenges that require sophisticated integration of prevention science, policy, and practice in the educational system. A central challenge focuses on systems integration across developmental stages. As empirically validated programs have accumulated and schools have begun adopting them at increasing rates (Ringwalt et al., 2002), schools are now searching for integrated models with a clear scope and sequence from pre-K through grade 12 (Collaborative for Academic, Social, and Emotional Learning (CASEL), 2003; Elias et al., 1997). At present, the field of prevention science has primarily implemented and assessed isolated programs that focus on relatively small segments of this age span. While much has been done at the elementary level, there is little in the way of comprehensive, evidence-based models that address multiple developmental levels. As the process of school reform grows, it will require not only integrating program models across developmental periods, but also greater sustained collaboration between researchers and practitioners to develop, implement, and evaluate these efforts (Greenberg et al., 2003).

Over the past 3.5 years, the JHU CPEI has supported the pilot and feasibility of the combined version of the PATHS (Kusche & Greenberg, 1994) and the PAX GBG (Embry et al., 2003) universal classroom-based interventions for students in grades K-5 in BCPSS. The goal of this model was to combine an intervention that supports teacher classroom management and student self-regulation (GBG) with an intervention that focuses on social emotional learning (SEL) skills acquisition in students (PATHS). This process has been very successful and resulted in a newly funded randomized controlled trial from IES to conduct a full-scale test of its efficacy. Feedback from teachers and administrators has been positive and has indicated a need for similar universal interventions in grades 6-8. Further, many urban educational systems, like BCPSS, are moving towards creating integrated neighborhood schools that extend from K through 8th grade. As a result, there is a need for universal preventive approaches that span these developmental periods.

Despite the need for universal classroom intervention in grades 6-8, a literature review (e.g. Greenberg, 2007; Spoth, Greenberg & Turrisi, 2008) suggests that there are very few universal preventive interventions for youth at this developmental stage and those that exist are primarily focused on drug prevention, rather than a broad range of more general SEL skills. Consequently, we are proposing to build on the JHU CPEI’s prior work to create a middle school adaptation of the combined model of the GBG+PATHS for use with students in grades 6-8. We are also proposing to integrate evidence-based lessons and practices from the Aban Aya Youth Project (AAYP), a culturally informed universal intervention designed to reduce risk for behavior problems among urban African American youth (Flay et al., 2004). PATHS, GBG, and AAYP were selected for inclusion based on prior evidence documenting effectiveness in late childhood, their focus on SEL skills that are the foundation of youth development and the prevention of adolescent problem behavior, and their cultural relevance to urban, African-American youth.

Specifically, the proposed pilot plans to address the following aims:

Aim 1: To create a developmental adaptation of the Good Behavior Game and PATHS (GBG+PATHS) that integrates the Aban Aya Youth Project (AAYP) to make the content of the program more developmentally appropriate for use with urban early adolescents in grades 6-8.

Aim 2: Determine the feasibility and acceptability of GBG+PATHS Middle School (MS) model through pilot interventions that receive intensive feedback from teachers and students.

Aim 3: To evaluate the impact of the GBG+PATHS MS model compared to care as usual on outcomes of adolescent problem behaviors including school misbehavior, aggression/violence, drug use, and unsafe sex.

Initiative Team Members and Leadership. The research team is lead by Dr. Ialongo, and includes Drs. Greenberg, Domitrovich, Embry, Gittlesohn, and Jagers. Cost evaluations will be overseen by Dr. Alexandre and the statistical analyses will be overseen by Dr. Scharfstein and assisted by the BCPSS Research Methodologist. See the Budget Justification for detailed descriptions of the research team members.

2. BACKGROUND & SIGNIFICANCE
2.1 The past two decades have brought clear progress and a stronger empirical base to the fields of school-based prevention (Greenberg et al., 2003). There are now a considerable number of empirically validated classroom and family-based curricula that have been shown to reduce mental health symptoms, substance use and their associated risk factors. Reviews and meta-analyses of prevention programs that address substance abuse (Blitz, Arthur & Hawkins, 2002; Tobler et al., 2000; Gottfredson & Wilson, 2003; Lochman & van den Steenhoven, 2002), violence and anti-social behavior (Elliott, 1998; Hahn, Fuqua-Whitley, Wethington, Lowy, et al., 2007; Wilson, Gottfredson, & Najaka, 2001; Wilson, Lipsey & Derzon, 2003), mental health (Durlak & Wells, 1997; Greenberg, Domitrovich & Bumbarger, 2001; Hoagwood et al., 2007), and positive youth development (Catalano et al., 2002) have shown that both universal and targeted prevention programs can substantially reduce the rate of problem behaviors and symptoms, as well as build protective factors that reduce further risk.

2.2 CASEL, a scientific group devoted to advancing the science and practice of SEL, identified five core groups of SEL competencies that represent desirable developmental outcomes for comprehensive SEL programs that also reduce risk for problem behaviors (CASEL, 2005). These include: 1) self-awareness, 2) self-management, 3) social awareness, 4) relationship skills, and 5) responsible decision-making. Evidence-based SEL programs teach these competencies intentionally, sequentially, and in ways that are developmentally appropriate. They establish contexts where these skills can be expressed, practiced, and encouraged throughout the day. Optimally, programs are implemented in a coordinated manner throughout the school, during out-of-school activities, and at home. By addressing the shared social and emotional variables that mediate risk reduction/positive behavioral outcomes across these approaches, SEL provides a coordinated, integrated framework for preventive interventions designed to promote student success (Elias et al., 1997). To enhance educational and social-emotional outcomes, SEL instruction and the related skill, knowledge, and attitude development should occur within a safe learning environment and facilitate the development of such an environment. Among the important structural features of school environments are: (a) safe and orderly school and classroom environments; (b) caring relationships between students and teachers that foster commitment and connection to school; (c) engaging teaching approaches such as cooperative learning and classroom management; and (d) adult and peer norms that convey high expectations and support for high-quality academic performance (Greenberg et al., 2003).

2.3 Program Descriptions.

**PATHS.** Promoting Alternative Thinking Strategies (Kusche & Greenberg, 1994) is a universal, teacher-taught classroom-based preventive intervention. It represent one of only a handful that have been shown in large scale, randomized controlled trials to have an immediate and beneficial impact (Conduct Problems Prevention Research Group, CPPRG, 1999; Greenberg et al., 1995; Kam et al., 2004) on aggressive/disruptive and off-task behavior. PATHS seeks to accomplish reductions in aggressive/disruptive and off-task behavior via teacher led instruction aimed at facilitating emotion regulation (particularly anger management), self-control, social problem-solving, and conflict resolution skills (Greenberg et al., 1995; Kam et al., 2004). The social-emotional skills targeted in PATHS are consistent with the 5 core competencies proposed by CASEL for healthy development.

**AAYP.** Aban Aya Youth Program (AAYP) is a culturally informed universal intervention designed to reduce risk for school misbehavior, violence, substance use, and unsafe sex among urban African American youth, grades 5-8. It includes a core classroom social development curriculum and school/family community intervention components. In a randomized trial study, intervention students showed reduced rates of violence, unsafe sex (including increased condom use), substance use, and school delinquency, compared to those in controls (Flay et al., 2004).

**GBG.** The Good Behavior Game (GBG; Barrish et al., 1969) is a universal, preventive intervention for use in elementary classrooms that has been shown to reduce aggressive/disruptive behavior in early elementary school classrooms (Brown, 1993; Dolan et al., 1993; Ialongo et al., 1999). Follow-up studies suggest that the effects of the intervention are maintained in middle school (Kellam et al., 1994a; 1994b) and early adulthood (Kellam et al., in press; Petras et al., in press). GBG is based on social learning principles and introduces new skills to teachers to reinforce students’ inhibition of aggressive/disruptive and off-task behaviors within a game-like context.

2.4 Rationale for GBG+PATHS Middle School Model. As empirically validated programs have accumulated and schools have begun adopting these programs at increasing rates (Ringwalt et al., 2002), schools are now searching for integrated models with a clear scope and sequence from pre-Kindergarten through grade 12 (CASEL, 2003; Elias et al., 1997). Children between the ages of 10 and 14 experience many predictable stressors and dramatic life changes including rapid body changes, cognitive maturation, and increased social pressures (Carnegie Council on Adolescent Development (CCOAD), 1989). All adolescents face decisions about choosing appropriate friends, resolving conflicts with peers, negotiating increased independence from parents, experimenting with alcohol or drugs, and having sex. While these are common experiences, the negative consequences of poor decision-making for youth from urban, under-resources communities can lead to especially serious physical, social, and emotional problems and negatively affect their current and future life chances. To become well-adjusted, productive
adults, adolescents on an healthy developmental pathway must accomplish the following: 1) find a valued place in a constructive group; 2) learn how to form close, durable human relationships; 3) feel a sense of worth as a person; 4) achieve a reliable basis for making informed choices; 5) know how to use the support systems available to them; 6) express constructive curiosity and exploratory behavior; 7) find ways of being useful to others; 8) believe in a promising future with real opportunities; 9) master social skills, including the ability to manage conflict peacefully; cultivate the inquiring and problem-solving habits of mind for life-long learning; 10) become ethical persons; 11) learn the requirements of responsible citizenship; and 12) respect diversity in our pluralistic society (CCOAD, 1995).

Urban children and youth face difficulties that may impede the development of the important social and emotional skills described above. Urban youth at high risk for aggression are more likely to live in unhealthy living conditions, attend schools with limited resources, live in neighborhoods with high crime, and have parents who are emotionally and financially stressed (Lambert et al., 2005). This accumulation of risk factors increases children’s risk for developing conduct problems in elementary and middle school, and undermines the development of important SEL skills that serve as protective factors against risk (Reid & Eddy, 1997). It also makes them more vulnerable in adolescence for developing an inter-related set of problem behaviors, including academic underachievement, school discipline problems, violence, unsafe sex, and substance use. Adolescent aggression and violence are often part of a larger complex of problem behaviors that, in middle school, predict school drop-out, especially in urban contexts where dropout rates range from 30-40% (Battin-Pearson et al., 2000). As such, there is a significant need for comprehensive universal preventive interventions for use with urban early adolescents in grades 6-8. The potential benefits of improved child behavior and well-being are both direct and long-term. Improved classroom behavior with peers leads to a better classroom and building atmosphere and fewer interruptions during teacher instruction, both of which influence academic achievement and school success (Felner et al., 1995). Broader and longer term benefits accrue from improvements in social relations and reductions in delinquency and antisocial behavior; school dropout and academic failure; and improved mental health. Building protective factors to promote good mental health has the potential to reduce multiple forms of later disease and/or poor outcomes. Finally, even if treatment is effective for those with identified disorders, only prevention can reduce the number of new cases. Universal programs are positive, proactive, and provided to all students independent of risk status. The proposed model has advantages in that it provides a single preventive intervention to reduce or prevent multiple problems and contributes to adaptive coping across an array of experiences and settings. The model may operate through ecological change and skill development as well as through peer support for positive choices. At present the field of prevention science has primarily assessed isolated programs that are used in traditional middle school contexts (health class only) and/or focus on a single risk behavior (substance use). Researchers and practitioners need to work together to consider how all the elements of evidence-based programs fit together in the context of a school-wide effort to reduce aggression/disruptive behavior and increase student school success (Osher et al., 2002).

There are a number of reasons why we expect additive, if not synergistic, effects as a result of combining GBG, PATHS, and AAYP. First, PATHS seeks to reduce aggressive/disruptive behavior via teachers’ facilitation of emotion regulation, self-control, social problem-solving, and conflict resolution skills (Greenberg et al., 1995), whereas the GBG helps teachers manage student behavior by reinforcing inhibition of aggressive and off-task behaviors within a game-like context (Embry et al., 2003). The combination provides students with an opportunity to practice self-regulation skills in emotion-laden situations. PATHS lessons promote cooperation and provide the language and strategies needed to resolve conflicts that may arise in the context of the GBG. Second, by increasing attention to task and reducing classroom disruption, GBG may facilitate the acquisition of the SEL skills taught in PATHS. Third, GBG may increase the likelihood that teachers will appropriately prompt and reinforce students’ newly acquired skills. Consequently, the PATHS skills would be better learned and more frequently employed. Fourth, the increased teacher and child success from the combined model should minimize teacher and child discouragement and subsequent failure to participate or comply fully with the intervention regimens.

The content of GBG+PATHS and AAYP complement one another, particularly for use with urban early adolescents in grades 6-8. For instance, the AAYP classroom social development curriculum provides a culturally grounded, identity-focused approach for framing PATHS’ emphasis on SEL for boys and girls. Further, PATHS’ focus on the five core SEL components identified by CASEL offers a foundation for AAYP’s developmentally and contextually appropriate attention to preventing substance use and unsafe sex. Substance use and unsafe sex are central concerns for urban youth in grades 6-8 (Brook et al., 2004). SEL core competencies will provide a foundation for discussions of substance use resistance through stress reduction and healthy male-female relations as a prerequisite for safe sex practices, for example. Finally, the focus of PATHS and GBG on building a positive climate in the classroom and school aligns with classroom and school-wide aspects of the AAYP school-family-community intervention. Positive peer and adult relationships increase school connectedness, which lessens emotional distress and problem behaviors and increases desirable academic, social and emotional outcomes (Brand et al., 2003).
3 PRELIMINARY STUDIES

3.1 GBG in Middle School. Although developed and tested in Pre-K through grade 5, there has been much need expressed for interventions in the middle grades (6-8). Over the past 2 years, the JHU CPEI supported initial development of the middle school GBG+PATHS materials. A team was formed consisting of 5 teachers familiar with the original PAX version of GBG, the Center Director, and three Program Facilitators/GBG+PATHS coaches. Dr. Dennis Embry also consulted with the team on potential changes and adaptations that could be made for the upper grades. Realizing that middle grade students have different needs, the language of the program was made more age appropriate to allow for a distinction in grades 6-8. The PAX GBG was piloted as part of the framework for the middle grades, now called “PAX House”. A number of developmental adaptations were made. For example, the former “Kid of the Day” is called the “MVP” or “Most Valuable PAX Leader”. In the lower grades, students receive “tootles” or compliments, whereas the middle school youth receive “PAX-it” notes. “Wacky Prizes”, which are the immediate rewards the younger grades receive after a PAX Good Behavior Game are called “fickle fortunes”.

3.2 PATHS in Middle School. Over the past 2 years a team of curriculum interventionists that are experts in PATHS have worked with Drs. Greenberg, Domitrovich and Embry to pilot PATHS lessons that are linked to GBG and relevant for the middle grades. The team developed a series of core lessons, had middle school teachers pilot them, and made revisions. Lessons focused on the following topics: positive social relations, communication skills, how to appropriately compliment others; causes of stress and healthy approaches to stress reduction; interpersonal problem-solving and the management of conflict resolution; positive leadership and how to decide whether someone is a leader they should follow. A goal of the proposed project is more development and refinement of lessons in coordination with AAYP and the ideas and activities included in GBG. Some of these topics are covered in AAYP and PATHS concepts will be integrated with developmentally appropriate topics that emerge during adolescence including the prevention of substance use and unsafe sex.

3.3 Aban Aya Youth Project (AAYP). AAYP examined the efficacy of two comprehensive risk prevention programs (classroom social development and school-family community) for urban African American youth grades 5-8. The project was guided by the Theory of Triadic Influences (Flay & Petraitis, 1994) which posits that risk and protective factors for youth problem behavior derive from three streams of influence: 1) socio-cultural factors that affect attitudes toward problem behaviors; 2) interpersonal factors that affect the social pressure adolescents experience to engage in problem behavior; and 3) intrapersonal factors that affect problem behavior-related self-efficacy or related avoidance skills. The AAYP social development curriculum featured 16-21 lessons in each of the 5 years of the trial. The program was designed as a culturally sensitive program to help youth avoid violence, provocative behavior, school delinquency, drug use, and unsafe sexual behaviors. It integrated African American communal values (e.g., unity, self-determination, and responsibility), teaching strategies (e.g., proverbs and cooperative learning) and instructional content (e.g., history and literature) to promote the cognitive-behavioral skills needed to: 1) foster self-esteem, empathy, stress management and goal-setting; 2) develop decision-making, problem-solving and conflict resolution skills; and 3) develop self-efficacy needed to resist peer pressure and negotiate interpersonal relationships. The school-family-community program condition combined the classroom curriculum with parental support, school climate, and community partnership components. The parental support component emphasized parent-child communication and reinforcement of skills taught in the classroom curriculum. Efforts were made to impact the school climate by working with school staff and community members to form a local school task force. The task force engaged students, families, school personnel, community advocates, and local businesses in modifying school policy and forging school-community partnerships to support school-based activities.

Evidence of AAYP Efficacy. In a randomized trial of 12 schools and 1,153 students that compared each of the AAYP intervention components to an attention placebo control, 5th through 8th grade boys in the social development classroom curriculum and family-school-community intervention conditions had reduced rates of violence, unsafe sex (including increased condom use), substance use, and school delinquency, compared to those in the attention-placebo control. These findings were most pronounced in the family-school-community condition (Flay et al., 1994). Subsequent studies of AAYP have focused on mediators of violence reduction effects. These indicate that intervention effects on boys’ violent behaviors were mediated by reductions in the intent to engage in violent behaviors, positive attitudes towards violence, and perceived peer violence (Ngwe et al., 2004). This is consistent with the notion that early adolescents are concerned with peer relations, peer pressure, and social comparison processes.

4. METHODS

4.1 Overview of the Research Design. As part of our Phase 1 efforts in Years 1 & 2, we will conduct an extensive review of the literature regarding developmental factors to be addressed during the early adolescent years. We will also hold a “Consensus Conference” which includes a panel of invited experts who will review the
developmental and prevention literature relevant to universal, selective, and indicated preventive interventions for students in grades 6-8 (see detailed descriptions in Operations Core of the current application). We will then review the theoretical models that serve as the foundation of each of the three interventions (GBG, PATHS, & AAYP) in order to specify a framework for integration of the interventions and identify areas where additional materials or activities are needed. Two sets of focus groups with key stakeholders (students and teachers) will be conducted during this phase. The first will be to gather input regarding the key issues relevant to the development of positive youth development and to generate ideas for curriculum content. The second will be to gather feedback on curriculum content and format, which will be used to revise and refine the curriculum. Phase 2 activities will be carried out in Year 3. This includes making final revisions to the integrated intervention and developing lesson manuals and training protocols. Once these materials are ready, a pilot of the new middle school intervention will be conducted in one K-8 school in each of two locations, Detroit (by Dr. Jagers) and Baltimore, targeting students in grades 6-8. Qualitative data (via another round of focus groups) will be collected from students and teachers regarding the acceptability, feasibility, and satisfaction with the program content. Phase 3 will take place in Year 4 and include a comparison of the integrated middle school intervention versus “instruction as usual” in 6 K-8 schools in BCPSS. Data will be collected on both implementation quality, pre/post-test assessments of key outcomes (e.g., aggression, delinquency, substance use), and mediators of behavior change among students (e.g., social-cognitive processing). Phase 4 focuses on summarizing the findings from the pilot through peer-reviewed publications and the preparation of an R01 to test the effectiveness of the middle school version of PATHS+GBG.

4.2 Phase 1: Overview of Adaptation & Development. The primary modifications to the standard PATHS+GBG program, originally designed for students (grades K-5), will be to ensure it is developmentally appropriate for early adolescents in grades 6-8. This process will begin in Year 1 when we conduct the previously mentioned Consensus Conference on developmentally appropriate preventive interventions for middle school students. This will be followed by a period of reviewing the theoretical models that serve as the foundation of each of the three interventions in order to specify a framework for integration of the curriculum materials and identify areas where additional materials are needed. For GBG, we will review social-learning and behavioral principals. For PATHS our review will include the Affective-Behavioral-Cognitive-Dynamic model of development (Greenberg & Kusche, 1996). For AAYP our review will include the Theory of Triadic Influence (Flay & Petronis, 1994). Year 2 will begin with a series of focus groups (4) with parents, teachers, and children designed to help the program developers better understand the unique challenges faced by urban early adolescents. The focus groups will be facilitated by Dr. Jagers in Detroit and Dr. Domitrovich in Baltimore, each of whom will be assisted by a co-facilitator. The co-facilitator will help with recruitment of participants, take notes during the focus group, and ensure that participants are reimbursed for their time. Following the first set of focus groups, the Curriculum Development Team (Jagers, Embry, Domitrovich, Greenberg, and a curriculum writer) will review the elementary PATHS+GBG, AAYP, and other relevant curricula to identify areas of overlap and points of divergence that need to be addressed for use with the target population. This will be followed by the second set of focus groups (4) with parents, teachers, and youth to gather feedback on the proposed scope and sequence of the curriculum, and to generate ideas for content, format, and activities. The information gathered in the focus groups, together with input from Drs. Embry and Greenberg, will guide the development of outlines for each module and lesson. The curriculum writer will draft lessons for each module, which will be reviewed by the Curriculum Development Team.

The first step in the intervention development process will be to conceptually integrate the two interventions. Our initial piloting of PATHS and GBG in middle school classrooms suggests that the basic structure of lessons and the game can successfully be retained with developmental modifications. PATHS has always emphasized the importance of both formal lessons and teacher generalization through the use of daily practices such as the PATHS Kid of the Day and dialoguing to promote self control and problem solving. The GBG provides an additional “practice” opportunity that compliments the explicit instruction provided by the PATHS lessons. PATHS addresses all of the skills included in the CASEL framework of social-emotional competence. This includes self-management which is a skill domain also targeted in the GBG and social-problem solving which is already the core approach utilized in AAYP. AAYP is a universal intervention that focuses on the developmental issues of early adolescence in a way that is culturally contextualized for urban, African-American youth. The focus of the intervention is on healthy behavioral choices as they apply to decisions about violence, substance use, and sexual behavior. As such, it targets the relevant content for a middle school universal curriculum that is designed to reduce poor outcomes in adolescence, but it could benefit from the broader social-emotional framework promoted by CASEL and reflected in curricula such as PATHS (e.g., focus on communication skills, self-control, emotional awareness). The language and strategies for promoting emotion knowledge, self control, and problem solving skills in PATHS will be integrated into AAYP substance use and safe sex content. For example, by exploring issues of personal and collective identity development, AAYP provides a frame for PATHS’ lessons on emotional awareness, anger and stress management,
conflict resolution, and leadership. PATHS’ treatment of social problem solving and decision making will inform AAYP’s attention to the hyper-sexualized portrayals of African American manhood and womanhood in popular culture. This serves as a precursor for discussing constructive male-female relationships and reproductive health.

4.3 Phase 2: Pilot in 1 BCPSS and 1 Detroit K-8 School. In Year 3, we will create an effective training model that prepares teachers to use the combined intervention. The second goal will be to pilot test the full set of integrated materials in 1 BCPSS K-8 school and 1 school in Detroit. The developers will take time to integrating their existing training materials around the rationale for the combined intervention. Training materials from each intervention that overlap will be combined. Large group and small group exercises will be created to supplement the lectures. Teachers in grades 6-8 in the 2 pilot schools will receive training in the curriculum as described below. This alpha version of the intervention will be implemented in each location. Feedback will be gathered from teachers in the form of focus groups, individual interviews, and anonymous questionnaires and used to revise the curriculum. Concurrent with the piloting of the PATHS+GBG program, a second round of focus groups (teachers, students, and parents) will be conducted by Drs. Jagers and Domitrovich regarding feasibility, acceptability, and satisfaction of the intervention which will be used to make additional modifications to the content and delivery of the intervention.

4.4 Phase 3: Feasibility & Acceptability Study in 3 BCPSS K-8 Schools. In Year 4, we will examine the feasibility and acceptability testing in 6 K-8 BCPSS schools (3 Intervention, 3 Control). Each school contains approximately 100 students at each grade level. A random sample of 50% of the students will be drawn from the total population (N=1800) resulting in a sample of approximately 900 students who will be included in the study. Participants will be 6th, 7th, and 8th grade students and their teachers. The assessments will involve anonymous youth surveys and teacher ratings of students at two time points (beginning and end of the school year). Measures of outcomes and mediators are described below.

**Initial Training.** Intervention teachers will participate in a 2-day training session led by Drs. Domitrovich and Jagers prior to the beginning of the school year. During the initial training, trainers will review all of the core elements of the adapted PATHS+GBG model, provide instruction on each core objective, and provide opportunities for teachers to role play the sessions.

**Coaching.** The coaching model calls for the coach to assist each teacher in setting up their classroom for implementing the intervention, modeling the intervention components for them, and then observing the teachers implementing the intervention on their own and giving them constructive feedback on their implementation. This will be completed within a month of the initial training. Drs. Embry, Domitrovich, and Jager will provide consultation to the on-site coach in this process. Following this initial phase of the coaching model, the intervention coach will be available onsite in each of the schools on a bi-weekly basis. In between on site visits, the coach will be available via e-mail and by phone on a more frequent basis as needed. The coach will continue to a) model the use of the PAX GBG and the PATHS lessons, b) provide in classroom guided feedback, and c) face-to-face, on-line, and telephone consultation. Our experience in our pilot and feasibility studies was that the coach could meet with teachers during planning periods to discuss their observations and provide feedback to teachers.

4.5 Measures of Implementation Fidelity.

**Coach Ratings.** A series of measures have been developed to monitor and ensure high quality implementation of the elementary PATHS+GBG intervention. These measures will be modified to be consistent with the adaptations made to the middle school PATHS+GBG program. A 22-item, Implementation Observation Rating (IOR) was developed for coaches to make monthly ratings of fidelity and quality of intervention delivery. Approximately 1/3 of the items assess more general aspects of the teacher’s classroom management and presentation skills. These items include teacher interpersonal style (e.g., teacher creates a positive and responsive atmosphere), level of punitive discipline (e.g., does not use punitive or shaming techniques), and teacher management and discipline skills (e.g., teacher provides clear structure, expectations, and routines and consistent discipline). The remaining items in each implementation fidelity rating scale are based on the protocol (or the “recipe”) teachers are encouraged to follow when playing GBG and doing a PATHS lessons. All the items are rated by the coach on a 5-point scale, from 1 (none of the identified characteristics or interventions elements) to 5 (the identified characteristics were highly evident and/or implemented with the highest degree of fidelity).

**Teacher Reports.** In terms of the GBG, teachers will report the number of games played each day, the length of the games in minutes, and the number of times each team won a game. Similarly, teachers will report on the number of PATHS/AAYP lessons taught, percentage of each lesson completed, ratings of what elements were most successful or inappropriate, and level of student participation and engagement. Teachers will be able to enter the data on a hard copy form supplied by the coach or can use the INSPIRE web-based, electronic system described in the preliminary studies section and developed with support from our ACISR (see description of INSPIRE in the Operations Core). Teacher Perceived of Intervention Attributes Scale-Prior to Implementation (TPIA-PRI). As described above, in addition to completing the training satisfaction questionnaire, participating teachers were also
asked at the conclusion of the training to complete an adapted version of the TPIA-PRI, which we developed as part of ACISR supported pilot and feasibility efforts. The TPIA-PRI consists of a series of questions regarding the program, including perceived need, developmental and cultural appropriateness, and ease of implementation. **Teacher Perception of Intervention Attributes Scale-Post Implementation (TPIA-PSTI).** The TPIA-PSTI assesses many of the same domains included in the Pre-Implementation version of scale, but expands the number of questions within those domains to reflect the fact that the teachers are better able to report on each of the elements of the PATHS and GBG interventions after having implemented the intervention. It will be administered following the implementation of the intervention.

**Observations.** Research assistants (RAs) will observe lesson implementation to independently assess the level of level of implementation fidelity and participant engagement in the selected lesson. Each lesson will be reviewed in advance to ensure the RAs have a complete understanding of lesson objectives and methodologies.

### 4.6 Measures of Intervention Outcomes.

The following measures will be administered to 900 students via anonymous surveys (450 treatment and 450 control) prior to randomization and at the end of the year-long pilot. The 5 CASEL dimensions of social-emotional skill will be assessed via the Perspective-Taking Scale of the Interpersonal Reactivity Index (Davis, 1993), which measures empathy. The Problem-Solving Measure for Conflict (Lochman & Lampron, 1986) and Reasoning about Substance Use and Sexual Situations (Flay et al., 2004) will measure the social problem solving. Students will report their association with deviant peers by responding to a 16-item scale taken from the JHU CPEI Youth Interview (Chilcoat, Dishion, & Anthony, 1995), which measures friends’ use of drugs, attitudes toward drug use, and involvement in delinquent behaviors. Students will report on their own behavior and emotional experiences by completing the Strengths and Difficulties Questionnaire which includes 4 scales: Emotional Symptoms, Conduct Problems, Hyperactivity/Inattention, Peer Problems, & Prosocial Behavior. Classroom climate will be assessed with the Classroom as a Caring Community, Student Voice, and Perspective-Taking Opportunities (Flanagan, Syvertsen & Stout, 2007). Students will also report on initiation and frequency of sexual activities (Flay et al., 2004). Teachers will complete an expanded version of the TOCA-R administered via the INSPIRE program, which includes standard TOCA-R items regarding aggressive/disruptive behavior and concentration problems, as well as emotion regulation problems, internalizing symptoms, prosocial behavior. This expanded version of the TOCA-R was tested by Drs. Leaf and Bradshaw in PBIS trials and has been shown to have high internal consistency and test-retest reliability (Koth et al., under review). Academic records (e.g., attendance, suspensions, academic performance) will also be gathered without identifiers and examined at the classroom level.

### 4.7 Phase 4: Disseminate Findings & Develop R01 Efficacy Trial.

In Year 5, we intend to summarize the findings from the pilot in a series of manuscripts which will be submitted for peer-review and presentations at professional conferences. Findings from the project will also be disseminated locally through presentations to BCPSS. The findings from the pilot will be used to calculate the sample size needed to power the proposed trial. We will also prepare and submit an R01 application to NIMH to conduct a larger scale efficacy trial of the middle school version of PATHS+GBG. In conclusion, the proposed study has the potential to address a significant gap in the extant research on evidence-based universal preventive intervention for early adolescents.

5. **DATA ANALYSIS**

5.1. **Analytic Approach.** We will examine the feasibility and acceptability data collected in Years 2-3 using descriptive analyses on the participant surveys and self-report satisfaction and feedback measures. The qualitative data will be summarized for development purposes. Common themes will be identified and grouped, and used to guide the development and refinement processes. We will use a mixed-model ANCOVA to compare the 2 conditions on the primary outcomes, as assessed in the spring with regression adjustment for fall baseline levels of the outcome measures. Condition and the fall aggressive/disruptive and off-task behavior scores will be included as fixed effects while school and child will be included as nested random effects. The null hypothesis of no intervention effect is assessed by testing the variation among the conditions against the average variation among schools within conditions (Murray, 1998). The influence of potential moderators (e.g., gender, grade level) will be explored.

1. **PRINCIPAL RESEARCH CORE INITIATIVE 3: A Universal Intervention to Prevent Depression among Middle School Students**

1. **SPECIFIC AIMS**

Consistent with the JHU CPEI’s mission to improve school-based preventive and early interventions among middle school youth, our third initiative will test the feasibility, acceptability, and preliminary impact of a universal intervention for depression among 6th graders. As Kellam and colleagues’ (1983) life course/social field theory suggests, middle school represents a key developmental transition period that can compromise children’s psychological and emotional well-being. Moreover, our integrated conceptual model also draws on Patterson et al.’s
(1992) “cascade model” which suggests that early antisocial behaviors are a precursor to and indirect cause of depressive symptoms that arise in later childhood or adolescence. Given the potential early onset and lifetime consequences of depressive symptoms, it is not surprising that the World Health Organization identified unipolar depressive disorders as the fourth leading cause of global disease burden in the year 2000 and the leading cause of disability in the Americas (Üstün et al., 2004). First onset of depression commonly occurs in childhood or adolescence, indicating the need for early detection and intervention (Kessler & Wang, 2008). Prevention and early intervention is critical because depression impairs optimal youth development, including successful academic performance and school completion (Blum et al., 2000; Boyce et al., 2002; DoSocio & Hootman, 2004). Furthermore, BCPSS youth have high rates of exposure to the stressors (e.g., community violence, single-parent homes, and histories of abuse) that create risk for depression (Brown, 2003; Brown, 2006; Gilman et al., 2003; Margolin & Gordin, 2000; Osofsky & Sheeringa, 1997). In addition to the risk associated with stress exposure, middle students are at a critical developmental stage when there is a heightened risk for depression. Depression is a significant problem among African American young adults in low-income Baltimore neighborhoods (Ialongo et al., 2004). At even earlier ages, this population is at high risk for poor school performance and premature school dropout, with graduation rates in the BCPSS as low as 36% (Maryland Report Card, 2007; Swanson, 2004).

PRC Initiative 2 targets a population at risk for depression - BCPSS 6th graders – using a universal prevention approach (Mrazek & Haggerty, 1994). We propose to adapt the Structured Psychotherapy for Adolescents Responding to Chronic Stress (SPARCS; Derosa et al., 2006) for use in the middle school setting. SPARCS was designed as a clinic-based treatment for urban African American adolescents responding to chronic stress. It has demonstrated good feasibility, acceptability, and outcomes with that population. SPARCS is based on cognitive behavioral theory and delivered in a group skills training format. It consists of 6 sessions held weekly and delivered by mental health professionals with optional co-facilitation by a community member. It has not yet been examined in a school-based setting, however, or as a preventive intervention for middle school students. We plan to implement SPARCS in 2 BCPSS middle schools. In each school, one classroom will be randomly assigned to receive SPARCS and a second classroom will be randomly assigned to a control condition. The intervention will be delivered during school hours in the school setting by a mental health clinician and a community member. The intervention will be assessed with respect to acceptability, feasibility, and effects on youth depressive symptoms, coping skills, and academic performance. We will then compare delivery of SPARCS by a mental health professional and community member with delivery by a community member only, to no-intervention control. These three conditions will be implemented within the two participating schools from Aim 1. We will assess whether co-facilitation by a mental health professional improves feasibility, acceptability, or outcomes. If found equally efficacious, we plan to develop a RCT (R01 grant application) to test the curriculum as delivered by a community member, as it would be more cost-effective and easily replicated in schools lacking access to mental health professionals. Given the number of public school students in low-income urban environments who are at risk for depression and poor academic outcomes, a school-based universal intervention has substantial relevance for dealing with a significant public health problem. Specifically, the proposed pilot plans to address the following research aims:

**Aim 1:** Make minor adaptations to the Structured Psychotherapy for Adolescents Responding to Chronic Stress (SPARCS) for use as a universal preventive intervention in a middle school setting.

**Aim 2:** Conduct a pilot study assessing the feasibility, acceptability, and outcomes of the school-based SPARCS program to prevent depression.

**Aim 3:** To conduct a three-arm pilot trial comparing two models of delivering the school-based universal intervention.

_**Initiative Team Members and Leadership.**_ Drs. Tandon and Mendelson will serve as Co-Team Leaders and will be joined by Drs. Leaf and Weist, and the BCPSS Intervention Coordinator. Cost evaluations will be overseen by Dr. Salkever and the statistical analyses will be overseen by Dr. Frangakis and assisted by the BCPSS Research Methodologist. See the Budget Justification for detailed descriptions of the research team members.

2. BACKGROUND AND SIGNIFICANCE

2.1 The first onset of mental disorders commonly occurs in childhood or adolescence. Half of all lifetime mental disorders initially occur before age 14 (Kessler et al., 2005). Given the recurrent nature of depression, adolescents who experience a depressive episode are more likely to experience later episodes in adulthood (Lewinsohn et al., 1999; Rao, Hammen, & Daley, 1999; Weissman et al., 1999). Depression during adolescence has also been shown to increase the likelihood of substance abuse, delinquency, academic and workplace difficulties, and suicide attempts (Gotlib, Lewinsohn, & Seeley, 1998; Le et al., 2003; Lewinsohn, Rohde, & Seeley, 1996;
Newman et al., 1996). An early-onset mental disorders also predicts early termination of schooling, particularly high school dropout (Breslau et al., 2008). Public schools in the United States graduate only about 70% of their students (Swanson, 2004), with many urban school systems graduating 60% or fewer and the BCPSS graduating only about 36% of its students (Maryland Report Card, 2007; Swanson, 2004). Data from the National Center for Education Statistics’ Common Core of Data indicate alarming dropout rates: from 1998-2002, a majority of ninth graders left school before graduation in many school districts, with dropout rates as high as 67% in some urban communities. Youth in lower income and minority communities are at highest risk for school dropout (Wald & Martinez, 2003).

2.2 School-based interventions have shown promise in preventing adolescent depression. Emerging evidence suggests that school-based interventions have beneficial effects in promoting positive adolescent mental health. A systematic review of Australian school-based prevention and early intervention programs for depression and anxiety found that a number of programs produced positive outcomes (Neil & Christensen, 2007). In the US, the Penn Resiliency Program (PRP) has shown promising outcomes for preventing depressive symptoms, although intervention effects were not uniformly positive across schools in a recent randomized trial (Gillham et al., 2007).

Few programs have targeted adolescents in low-income areas or African-American adolescents. A trial of the PRP intervention effects were not uniformly positive across schools in a recent randomized trial (Gillham et al., 2007). In the US, the PRP program to Latino and African-American children showed benefits for the Latino children but not the African-American children at both six-month and two-year follow-up assessments (Cardemil et al., 2007).

2.3 Skills adapted from cognitive-behavioral therapy (CBT), an effective treatment of depression for adolescents, have been used in the creation of effective preventive interventions for adolescents. Our intervention incorporates CBT strategies because they have proven effective in treating and preventing adolescent depression (Horowitz & Garber, 2006; Gillham et al., 2000). The intervention highlights stress, cognitive restructuring, and engaged coping strategies, three constructs central to CBT for depression. Considerable data demonstrates a link between stressful events and depression in adolescents. Research has identified three types of stressors that are particularly salient for low-income adolescents living in urban environments: (1) major life events (family member’s death), (2) chronic stressors (poverty, community violence), and (3) personal and amorous relationships (Garber, 2006). Several effective depression prevention interventions have used cognitive restructuring techniques to modify negative ways of perceiving events (e.g., Clarke et al., 2001) and have promoted engaged coping strategies, such as problem solving and distraction (Garber, 2006).

2.4 Schools are increasingly being utilized as sites for prevention and treatment interventions, yet research on the applicability and effectiveness of mental health-focused interventions in middle schools remains scarce. Emerging evidence suggests that school-based interventions have beneficial effects in promoting positive adolescent mental health (Gillham et al., 2007; Neil & Christensen, 2007). However, few programs have targeted African-American adolescents. The recent SAMHSA report to Congress (SAMHSA, 2007) highlighted both the promise of school-based interventions and the need for more research. Studies conducted by JHU CPEI affiliated faculty have demonstrated the benefits of early school-based interventions (Kellam et al., 2008; Poduska et al., 2008; Wilcox et al., 2008). Less research has focused on preventive interventions for middle school-aged youth.

2.4 Structured Psychotherapy for Adolescents Responding to Chronic Stress (SPARCS) is a skills-based curriculum designed to assist urban adolescents and young adults ages 12-22 living with high levels of stress. SPARCS is based on 3 empirically-validated interventions that were adapted and integrated for use with adolescents exposed to chronic stress: (a) Dialectical Behavior Therapy for Adolescents (Miller, Rathus, & Linehan, 2007), (b) Trauma Adaptive Recovery - Group Education and Therapy (Ford, Mahoney, & Russo, 2004), and (c) School-Based Trauma / Grief Group Psychotherapy Program (Saltzman, Pynoos, Layne, Steinberg, & Aisenberg, 2001) The SPARCS curriculum has been used widely with promising results, including with low-income urban African American adolescents. Significant improvements were reported in depression, anxiety, hopelessness, self-harm, and overall PTSD symptoms (Labruna et al., 2007). SPARCS has not yet been offered in a school-based setting or as a preventive intervention with middle-school students.

2.5 Potential Significance of a School-based Version of SPARCS. Young people in low-income urban environments must negotiate extremely stressful circumstances, often without adequate coping skills or resources. Adolescent onset of depression is common in the U.S. and is associated with multiple adverse outcomes, including a reduced likelihood of completing high school. School-based services and community mental health clinics do not have the capacity to adequately address a problem of this scope. Preventing depression and ameliorating dysfunction caused by elevated depressive symptoms can provide substantial educational benefits due to fewer missed school days and premature school terminations and can promote cost savings due to fewer healthcare visits. Our intervention also holds promise for replication on a larger scale. If, as expected, we improve depression and academic outcomes among urban public school students, we will be prepared to extend the model to other school-based settings in Baltimore and nationally.
3. PRELIMINARY STUDIES

3.1 Preliminary research by Drs. Tandon and Mendelson focused on developing a modified version of the SPARCS curriculum for use with an African American adolescent and young adult out-of-school population in an employment and training program setting (Mance, Mendelson, Tandon, Byrd, & Jones, in preparation). The modified curriculum is found in Appendix PRC3. The intervention was delivered by peer leaders with a mental health clinician present. The peer leaders assisted in the adaptation of the SPARCS curriculum for our target population and received ongoing training and supervision in group facilitation. In a pilot trial of the intervention, we found increases in positive coping strategies between baseline and post-intervention assessment (pre-intervention $M = 10.2$, post-intervention $M = 12.5$), with the largest increases for active coping and support section coping. We also found that depressive symptoms were unchanged from baseline ($M = 21.3$) to the mid-group assessment ($M = 21.3$), with symptoms declining at the post-intervention assessment ($M = 20.1$). These findings suggest that our peer-led cognitive behavioral intervention was successful in preventing the increase of depressive symptoms among adolescents and young adults who are disconnected from school and the workforce.

4. METHODS

4.1 Overview of the Initiative. Phase 1 will involve minor modifications to the SPARCS curriculum for implementation in school setting rather than a clinic. In Phase 2, we will implement SPARCS in 2 BCPSS middle schools. The intervention will be delivered during school hours in the school setting by a mental health clinician and a community member. In Phase 3, we will conduct a larger three-arm randomized pilot trial comparing two models of intervention delivery mental health professional and community member versus delivery by a community member only. Phase 4 of the project focuses on summarizing the findings from earlier phases through peer-reviewed publications and the preparation of an R01 to test the effectiveness of the school-based SPARCS program. A timeline for the core study activities is provided in Appendix PRC3. Phases 1 and 2 will take place in Year 3 of the Center grant, Phase 3 will take place during Years 4-5, and Phase 4 will take place during Year 5.

4.2 Details of the Design.

**Phase 1: Minor Adaptations to the SPARCS Curriculum.** Given that the SPARCS curriculum was designed for African American adolescents living in an urban context, we expect the content and methods will be appropriate for the middle school students targeted in this proposal. The primary adaptation will focus on the implementation of this clinic-based program in a school setting for a non-clinical population. Modifications will also be made so that the program can be administered by both mental health professional and community members. We will rely on our extensive experience with successful prevention curricular modifications and adaptations in BCPSS to ensure that the program has a good contextual fit within these schools and will be implemented with high fidelity. The school-based mental health clinicians from the Johns Hopkins Hospital Department of Psychiatry and the University of Maryland Department of Psychiatry who participated in the JHU CPEI pilot studies in BCPSS elementary schools will assist with any needed adaptations, and serve as the clinicians delivering the intervention in Phases 2 and 3 of the proposed Initiative. The research team and adaptation process will also benefit by participating in the Year 1 Consensus Conference regarding evidence-based preventive interventions for youth during the middle school years.

**Phase 2: Two-Arm Pilot Trial Comparing Two Intervention Delivery Methods.** Two public middle schools in BCPSS will be recruited, one of which will be a traditional middle school (6-8) and the other a K-8 school. In each school, one classroom will be randomly assigned to receive the intervention (i.e., the SPARCS curriculum) and a second classroom will be randomly assigned to a control condition. The intervention will consist of 6 1-hour sessions delivered in consecutive weeks during school hours, which focus on 6 core skills that promote positive appraisals of stressful situations and enhance coping: 1) SOS (identifying feelings and emotions); 2) Thing that Mess “U” Up (identifying stressors); 3) Mindfulness (cultivating awareness); 4) Let ‘M Go (problem solving and creating meaning); 5) Distress Tolerance (coping in the moment); and 6) Make a Link (communication and relationship skills). Each session will be co-facilitated by a school-based mental health professional and a community member. Drs. Mendelson and Tandon will train the mental health professionals and community members to deliver the intervention protocol; will ensure fidelity prior to starting the study through videotaped coding of adherence to the protocol; and provide weekly supervision. The mental health professionals will be school-based clinicians noted above. Community members will be adult or young adults from the community. Demographic, psychological, and academic factors will be assessed at baseline and post-intervention (see data collection table in Appendix PRC3).

**Study population and sampling design.** BCPSS data indicate that nearly 100% of students are African American. We anticipate approximately equal numbers of boys and girls in participating classrooms. Given this study’s universal intervention approach, all sixth graders in participating classrooms at the study sites will be eligible for study enrollment regardless of their score on our baseline mental health assessments. However, youth who report suicidal ideation will be immediately assessed for suicide risk by our research staff and will be referred to the school
mental health clinician as needed. We expect that each classroom will contain approximately 30 6th grade students, resulting in a total of 120 6th grade students eligible for study participation across the four classrooms. We will use recruitment strategies similar to those used by Dr. Leaf in other school-based interventions in Baltimore City to obtain parental consent and student assent. Of the 120 6th grade students eligible for study participation, we estimate that 80% (n = 96) will be interested in joining the study and return parent consent and student assent forms. We anticipate that 86 participants per group (90% of 96) will complete post-intervention assessments. Precautions will be taken to minimize study attrition, including emphasis on consistent group attendance and remuneration for each completed assessment.

**Phase 3: Three-Arm Pilot Trial Comparing Two Intervention Delivery Methods.** The two public schools recruited for Phase 2 will participate in Phase 3 during the following year. In each school, three 6th grade classrooms will be randomly selected to receive the intervention as usual (i.e., delivered by a school-based mental health professional and community member), the intervention delivered only by a community member, or a no-intervention control condition. The intervention will be the same length and content as described above, although slight modifications may be made based on the previous pilot findings. Demographic, psychological, and academic factors will be assessed at baseline, post-intervention, and 6-month follow-up.

**Study population and sampling design.** The study population will be the same as described above. We anticipate that 6th grade classrooms will contain approximately 30 students each. Given that we will be selecting 3 classrooms from each participating school, we expect to have a total of 180 students eligible for study participation. We estimate that 80% (n = 144) will be interested in joining the study and return parent consent forms, yielding 72 study participants at each of the four schools, with 38 participants within a given study arm at each school. We anticipate that 130 participants (90% of 144) will complete post-intervention assessments. Of those 130, we project that 117 participants (90% of 130) will complete 6-month follow-up assessments.

**Phase 4: Disseminate Findings & Develop R01 Efficacy Trial.** In Year 5 of the center, we intend to summarize the findings from the Phase 2 and 3 pilot studies in a series of manuscripts which will be submitted for peer-review. Findings from the project will also be disseminated locally through presentations at the BCPSS Practice Network. The findings from the pilot studies will be used to calculate the sample size needed to power a subsequent R01 application to NIMH to conduct a larger scale effectiveness trial of the school-based SPARCS curriculum. In conclusion, the proposed study has the potential to result in a universal preventive intervention for adolescents at increased risk for depression, which can be efficiently implemented in a school setting.

**4.3 Data Collection and Measurement for Phases 2 and 3.**

**Feasibility and Acceptability Measures.** To assess the feasibility and acceptability of SPARCS, we will collect data on (a) study recruitment, (b) attendance at treatment and control group sessions, (c) follow-up assessment rates, and (d) fidelity of intervention implementation.

**Outcome Measures.** Participant outcomes will be assessed at baseline and post-intervention in Phase 2, and at baseline, post-intervention, and 6-month follow-up in Phase 3. In both phases, baseline data will be collected via structured interview a week before the intervention is delivered. Data collection will occur in the school setting, and participants will receive a $10 honorarium at each assessment. We will collect data in 6 areas: (a) depression, (b) other mental health outcomes, (c) stress and coping, (d) behavioral controls, (e) academic performance, and (f) demographics (see Table 2). Measures were selected on the basis of reliability, validity, appropriateness for an urban African American population, and prior use in mental health research with adolescents. Many of these measures are currently being used by Drs. Tandon and Mendelson in their study examining the mental health status of out-of-school adolescents in BCPSS; the interview guide from this study is found in Appendix PRC3, along with a timeline for the core data collection elements and a paper summarizing prior research using these measures.

**5. DATA ANALYSIS**

**5.1 Assessment of Feasibility and Acceptability.** Phase 2 will evaluate the feasibility and acceptability of our cognitive-behavioral intervention. Group attrition rates will be calculated by assessing the percentage of study participants enrolled in our study who attend the majority (> 5) of intervention sessions. Follow-up assessment rates will be calculated by determining the percentage of study participants in both the treatment and control group who complete the post-intervention assessment. Fidelity of implementation will be assessed using a Fidelity Checklist that identifies key topics and activities to be covered during each of the intervention sessions. Drs. Mendelson and Tandon will complete this checklist for each session.

**5.2 Assessment of Participant Outcomes.** Phase 2 will assess outcomes associated with SPARCS. Data analysis will be performed using an intent-to-treat model, with intervention group (treatment vs. control) as the independent variable and CDI scores as the primary dependent variable. Secondary dependent variables include cognitive appraisals and engaged coping strategies. Initial descriptive analyses will be conducted. Our continuous
depression measure (the CDI) will be examined for intervention effects using linear regression analysis while controlling for relevant covariates. We will examine condition X time (intervention effect) and number of intervention sessions x time (intervention participants only). We will use a similar analytic approach in examining indices of academic performance, as well as cognitive appraisals and coping strategies. Although our primary study outcome is depression, we will also examine the effects of our cognitive-behavioral intervention on anxiety and post-traumatic stress disorder symptoms. Phase 3 will compare intervention delivery co-facilitated by a school-based mental health professional and community member, delivery by a community member only, and a no-intervention control condition. Data analysis will be performed using an intent-to-treat model, with condition (clinician co-facilitation, community member facilitation, control) as the independent variable and CES-D scores as the primary dependent variable. The same analytic techniques and range of dependent variables will be used as in Phase 2. Although our sample size will not allow us to draw strong conclusions, we will also examine the differences in the incidence of depressive episodes among the three study groups at our 6-month follow-up.

This study examines the preventive effects of SPARCS (i.e., does the intervention keep depression from getting worse?). However, because SPARCS was initially developed as a treatment intervention, we believe it is appropriate to include adolescents already exhibiting depressive episodes in our study. Moreover, we believe that excluding students already exhibiting depressive episodes would reduce the feasibility of future implementation, given the need to screen for existing disorder. Thus, for Phase 2 and 3, our analyses will explore intervention effects for both the entire sample and the subsample of adolescents who have not yet experienced a depressive episode (as indicated by baseline depression scores). We will exclude adolescents experiencing a depressive episode at baseline from our analyses examining the incidence of depressive episodes.

5.3 Study Power. The primary outcome for Phases 2 and 3 is depressive symptomatology. For Phase 2, we will have approximately 70% power to detect a difference in mean CDI scores of 3 points among participants in our two study conditions (n=43 per group) at post-intervention using a two-tailed alpha of 0.05. This calculation assumes a standard deviation of 9.0, based on previous studies using the CDI with African American adolescents. A 3-point difference in CDI scores is a moderate effect size (0.50), as defined by Cohen (1988). For Phase 3, we will have approximately 85% power to detect a difference in mean CDI scores of 3 points (moderate effect size of 0.50) among participants in our three study arms (n=39 per group) at our 6-month follow-up using a two-tailed alpha of 0.10 with estimated standard deviation of 9.0.

1. PRINCIPAL RESEARCH CORE INITIATIVE 4: Middle School Coping Power: An Indicated Preventive Intervention for Early Adolescence

SPECIFIC AIDS

Over the last 3.5 years, the JHU CPEI has supported the pilot and feasibility testing of Lochman and Wells's (1996) Coping Power Program, an indicated preventive intervention, with fourth and fifth graders attending urban elementary schools in BCPSS. In response to the shift toward increased usage of K-8 (combined elementary and middle) schools in urban communities and the extant research indicating an increased risk for involvement in aggressive/disruptive behavior during the late childhood years (Moffitt, 1993; Patterson et al., 1989), we propose to derive an indicated preventive intervention of Coping Power for use with students in Grades 6-8. A review of several meta-analyses and summaries of evidence-based prevention programs (e.g., Mihalic et al., 2004; Hawkins & Catalano, 2004; Greenberg et al., 2001; Kutash et al., 2006; SAMHSA, 2008; Rones & Hoagwood, 2000; Wilson & Lipsey, 2007) revealed that there is a paucity of indicated preventive interventions for aggressive/disruptive behavior which have been shown to be effective for early adolescents. Prior randomized trials of Coping Power have shown that, relative to members of a comparison group, participants experienced lower rates of substance use, reductions in proactive aggression, improved social competence, and greater teacher-rated behavioral improvement among children in late childhood (grades 4-5) (Lochman & Wells, 2002b). Coping Power was selected for extension to the middle school years based on prior research documenting its effectiveness in late childhood (through grade 6); its focus on contextual, social-cognitive factors associated with aggressive behavior during the early adolescent years (Moffitt, 1993; Patterson et al., 1989); as well as our own pilot work showing Coping Power to be feasible and acceptable for use in BCPSS elementary schools.

However, some concerns remain regarding the level of parental involvement in the parent component of Coping Power, as well as the generalizability of the skills developed in the child Coping Power sessions across school and home settings. Connecting elements of the Coping Power child intervention with the whole school PBIS model may enhance generalizability of the skills developed during the Coping Power sessions for use in other school settings. Enhancing the parental engagement in the parenting sessions may also promote greater participation in the parent and child sessions. An alternative method for increasing parental and youth involvement and engagement in the preventive program is to deliver the Coping Power content via an individually-tailored or adaptive format (Collins,
Murphy, & Bierman, 2004). Dishion and colleagues’ Family Check-up (FCU), an assessment-driven and individualized intervention for promoting parent motivation, is one such adaptive platform through which the parent and child content of the Coping Power program could be delivered (Dishion, Nelson, & Kavanagh, 2003; Dishion & Stormshak, 2007). The FCU holds promise as an effective strategy for increasing child and parent participation and engagement in the change process. Consequently, we are proposing modifying the standard Coping Power indicated preventive intervention by (1) addressing developmental issues; (2) strengthening parent engagement activities; and (3) linking the content of the child program with school-wide PBIS in order to increase the program’s effectiveness for preventing antisocial behavior and substance use in grades 6-8 (referred to as Middle School (MS) Coping Power). We also plan to create and test an alternative delivery system for providing parents and children the content of MS Coping Power, using an individually-tailored adaptive preventive intervention platform (referred to as FCU/Tailored Coping Power). Both versions of the Coping Power program (MS Coping Power and FCU/Tailored Coping Power) will be developed and pilot tested to examine feasibility, acceptability, and outcomes. Specifically, the proposed pilot plans to address the following research aims:

Aim 1: Create an adapted version of the Coping Power program for middle school children (MS Coping Power), which includes content that is more developmentally appropriate for use with urban early adolescents in grades 6-8; enhancements for increasing parent participation and engagement; and augmentations that link it with school-wide Positive Behavioral Interventions and Supports (PBIS) to increase generalizability of the skills learned during the child sessions.

Aim 2: Deliver the content of the MS Coping Power intervention via the individually-tailored Family Checkup (FCU/Tailored Coping Power) in order to increase parent and child engagement and participation.

Aim 3: Determine the feasibility and acceptability of the standard MS Coping Power and FCU/Tailored Coping Power interventions and evaluate their impact compared to “care as usual.”

Initiative Team Members and Leadership. Dr. Bradshaw will serve as Team Leader and will be joined by Drs. Ialongo, Lochman, Boxmeyer, Reinke, Herman, Hoagwood, Weist, Gittlesohn, and Dishion. The BCPSS Intervention Coordinator will facilitate collaborations with the BCPSS and school-based mental health clinicians. Cost evaluations will be overseen by Dr. Alexandre and the statistical analyses will be overseen by Dr. Stuart and assisted by the BCPSS Research Methodologist. See the Budget Justification for descriptions of the researchers.

2. BACKGROUND & SIGNIFICANCE

2.1 Over the last decade, multi-component interventions with elements directed toward aggressive and disruptive preadolescent children and their parents have been found to be efficacious in reducing children's aggressive and disruptive behaviors (CPPRG, 2002; Hawkins et al., 1992; Walker et al., 1998; Webster-Stratton & Hammond, 1997). One such multi-component program is Coping Power (Lochman & Wells, 1996), which applies a contextual social-cognitive framework that addresses both the parenting processes and children's sequential cognitive processing. Prior research indicates that aggressive children have cognitive distortions at the appraisal stage of social-cognitive processing because of difficulties in encoding social information and in accurately interpreting social events and others' intentions. They also have cognitive deficiencies at the problem solution stage of social-cognitive processing by generating maladaptive solutions for perceived problems and having non-normative expectations for the usefulness of aggressive and nonaggressive solutions to their social problems (Bradshaw & Garbarino, 2004; Lochman & Dodge, 1994, 1998). Schemas involving children's expectations of others can have a significant impact on the information processing steps within the social-cognitive model for aggressive children (Lenhart & Rabiner, 1995; Seifer et al., 1992). The contextual social-cognitive model also emphasizes parenting processes in the development and escalation of problem behaviors. As described by Patterson, Reid, and Dishion (1992), child aggressive behavior arises most fundamentally out of early experiences with parents who provide harsh discipline, have poor problem-solving, vague commands, and poor monitoring (also see Capaldi & Patterson, 1991; Dishion & McMahon, 1998; Patterson et al., 1989).

2.2. Description of the Coping Power Program. Dr. Lochman and Wells’s (1996) original Coping Power Program was directed at children in the late elementary school years and middle school transition. The multi-component intervention provides training in social skills and social problem-solving. It includes parent and child components which address the social-cognitive factors and mechanisms involved in aggressive/disruptive behavior problems which are delivered over 1 to 1.5 academic years (Lochman & Wells, 2004).

Child component. The child component of Coping Power features 33 group sessions, which average in size from 4 to 6 children, typically take place at the child’s school, and last about 45-50 minutes. In addition to group sessions, Coping Power includes 10-12 individual 30-minute sessions at the child’s school (averaging once per
month). The individual sessions are used primarily for monitoring and reinforcing children’s attainment of classroom and social behavior goals (e.g., avoiding fights with peers, resisting peer pressure). The child component focuses on teaching children: (a) to use self-statements as well as relaxation and distraction techniques to cope with anger arousal; (b) to identify one’s social goals in problem situations, to generate alternative solutions to such problems, and to consider the short and long term consequences of those solutions; (c) to develop friendships with non-deviant peers, and to enter new non-deviant peer groups; and (d) to cope with peer pressure. The methods employed in teaching children these skills include viewing videotapes of children modeling their use when they become aware of their anger. In addition, children plan and make their own videotape of inhibitory self-statements and social problem-solving with problems of their own choice. Finally, negotiation and cooperation skills are taught within the context of structured and unstructured interactions with peers.

**Parent component.** The parent component consists of 16 parent group sessions during which parents meet in groups of 10-12 with two co-leaders. The content of the Coping Power parent component is derived from social learning theory-based parent training programs developed and evaluated by prominent clinician-researchers in the field of child aggression (Forehand & McMahon, 1981; Patterson et al., 1992). Over the course of the 16 sessions, parents learn the following skills: (a) identifying prosocial and disruptive child behaviors; (b) rewarding appropriate child behaviors; (c) giving effective instructions and establishing age-appropriate rules and expectations for their children in the home; (d) applying effective consequences to negative child behaviors; (e) assisting parents to better monitor and supervise their children’s behavior; (f) managing child behavior outside of the home; and (g) establishing ongoing family communication structures in the home (such as weekly family meetings). In addition to these “standard” parenting skills, parents also learn additional skills that support the social-cognitive and problem-solving skills that children learn in the Coping Power child component. These parent skills are introduced at the same time that the respective child skills are introduced, so that parents and children can work together at home on what they are learning. For example, parents learn to set up homework support structures and to reinforce organizational skills around homework completion at the same time that children are learning organization skills in the Coping Power child component. Parents also learn techniques for managing sibling conflict in the home at the same time that children are addressing peer and sibling conflict resolution skills in the group. Additionally, parents learn to apply the problem-solving model to family problem solving so that child skills learned in the group will be prompted and reinforced in the family context. A final module of the Coping Power parent component includes sessions on stress management for parents.

### 2.3. Evidence of the Efficacy of Coping Power.

Coping Power has been acknowledged as a SAMHSA Effective Program and a NIDA Research-Based Prevention Program (Hawkins & Catalano, 2004). Further, the Coping Power Program is one of very few indicated interventions described in Greenberg et al. (2001) to have evidence of beneficial intervention impact at one-year follow-up in two separate trials (Lochman & Wells, 2003, 2004). The efficacy of the Coping Power program has been demonstrated in NIDA- and SAMHSA-funded trials. Briefly, in the NIDA-funded study, boys were randomly assigned to one of the following conditions: a cognitive-behavioral Child Group Component; a Combined Child Component; a Behavioral Parenting Training Component; and an untreated cell. The 15-month intervention took place during fourth-fifth grades or fifth-sixth grades. Analyses of potential mediating processes at the end of the intervention period indicated that Coping Power had broad effects on aspects of boys’ social information processing (attributions, social goals, outcome expectations, and perceptions of others); locus of control; temperament (fearfulness, sensation-seeking); and their perceptions of their parents’ consistency in parenting. Analyses of the one-year follow-up data indicated that, in comparison to the high-risk control condition, the intervention reduced children’s delinquent behavior; alcohol and marijuana use; and was associated with improvements in their teacher-rated functioning at school (Lochman & Wells, 2002a; 2004).

Based on these efficacy findings, Lochman and Wells conducted an effectiveness study to examine the effects of Coping Power (combined child and parent components) as an indicated preventive intervention directed at high risk aggressive children, along with the effects of a universal preventive intervention (Lochman & Wells, 2002b). The Universal intervention consisted of a series of teacher in-service meetings and classroom-wide meetings for parents about the upcoming middle school transition. Students in fourth grade were randomly assigned to 1 of 4 conditions: (1) Indicated Intervention and Universal Intervention; (2) Indicated Intervention and Universal Control; (3) Indicated Control and Universal Intervention; and (4) Indicated Control and Universal Control. At post-intervention, the 3 intervention conditions produced lower rates of substance use than did the control (Lochman & Wells, 2002b). This significant intervention effect for substance use was consistent with the findings from the NIDA-funded efficacy study of an earlier version of Coping Power, called Anger Coping. All three intervention groups also showed significant positive effects in social competence, self regulation, and parenting practices (Lochman & Wells, 2002b). Children who received both interventions displayed improvements in their social competence, and teachers rated these children as improving most in problem solving and anger coping. The children receiving both
interventions also tended to display less pronounced anger in response to vignettes about social problems, and they tended to have greater decreases in teacher-rated aggression over time. Coping Power alone also produced significant reductions in parent- and teacher-rated proactive aggression. Additionally, teachers reported significant improvements in overall behavior for the Coping Power children at post-intervention. At a 1-year follow-up, Coping Power children were significantly lower than controls on teacher-rated physical aggression and self-reported substance use and delinquency (Lochman & Wells, 2003). Recent analyses have found that Coping Power continues to have significant positive effects on teacher-rated aggression and on substance use among the cohort’s older children after 3 years (Lochman, Chen et al., 2006).

2.4. Rationale for Middle School (MS) Version of Coping Power. The standard Coping Power program has been tested in randomized controlled trials with fourth through sixth graders to help prepare these students for the transition to middle school. Yet there is increasing interest in the use of multi-component preventive interventions, like Coping Power, for children during the transition to adolescence, when the risks for involvement in aggressive behavior and substance use are increased (Bierman, 1996; McMahon & Slough, 1996). Specifically, there is an increase in contextual risk, such as their neighborhood environment or the presence of substance use in their home, which can influence many of the familial and peer pressures that are placed on adolescents (Jessor, 1991). Youth who are exposed to violence in the community or at home are at increased risk of displaying externalizing and/or internalizing problems (Cooley-Quille et al., 2001). Aspects of family management (such as parental monitoring, behavior management strategies, and family cohesion and conflict) either can buffer children from these contextual influences or increase their risk for later substance use and other problem behaviors (Ary et al., 1999; Chilcoat & Anthony, 1996; Dishion et al., 1995; Patterson, et al., 1989). The formation of maladaptive social information processing patterns is a significant component in the developmental trajectory that leads to aggression, peer difficulties, and subsequent substance use and other adolescent problem behaviors. Researchers have found that falsely attributing anger and hostility to others, failing to generate prosocial or verbally assertive alternatives to social situations, and other maladaptive patterns of social information processing leave a child likely to engage in negative peer interactions, leading to aggressive encounters and low social status (Crick & Dodge, 1994; Dodge et al., 1995). Aggression in childhood often co-occurs with the early onset and later frequent use of substances. It represents, along with peer influences, one of the strongest proximal risk factors for substance use and other problematic behaviors (Lochman & Wayland, 1994; Reiner et al., 2000; Van Kammen et al., 1991). Furthermore, association with deviant peers is one of the strongest proximal predictors of aggressive behavior and substance use during adolescence. Multiple studies indicate that children and adolescents who associate with deviant peers are at increased risk of using substances (Ary et al., 1999; Patterson, Dishion, & Yoerger, 2000; Thornberry & Khron, 1997). We propose to make a series of adaptations to the standard Coping Power program to address these developmental factors which are critical during early adolescence.

2.5. Rationale for Augmentations through PBIS. While prior research on the Coping Power program shows promise for use with 6-8th graders, the standard model could also benefit from augmentations to increase generalization of both the social-emotional and behavioral skills developed during the child group intervention to classroom and non-classroom settings. As noted previously, there is increasing interest in use of the universal school-wide PBIS program as a whole-school strategy for behavior management. While there is evidence emerging regarding the effectiveness of PBIS at reducing the overall levels of disruption (Barrett et al., 2008; Bradshaw et al., under review; Horner et al., in press), there remains a need for more intensive preventive interventions for children who do not respond adequately to the universal PBIS model. Coping Power’s focus on social-emotional and behavior problems for children with increased behavioral risk makes it an ideal program to pair with PBIS. In turn, the school-wide structure and systematic reinforcement systems offered by PBIS could help extend and generalize the skills developed in the Coping Power child sessions to other non-group settings, such as the classroom and cafeteria where adolescents are at increased risk engaging in disruptive behavior (Irvin et al., 2006).

2.6. Rationale for Using the Family Check-up (FCU) as an Alternative Platform for Delivering Middle School (MS) Coping Power Content. Another aspect of the standard Coping Power model which could be enhanced is parent participation and engagement in the parenting component. Although prior research indicates that parents’ participation in 3 or more sessions is associated with significant improvements in child outcomes, the overall level of parent participation tends to be rather low (Wells, Lochman, & Lenhart, 2008). Moreover, in our current feasibility trial of Coping Power in BCPSS elementary schools, parent attendance at the sessions was a significant challenge. We anticipate that parent participation may serve as an even greater issue for MS Coping Power, as research indicates that parent participation in school activities declines during the middle school years (Dauber & Epstein, 1993). To address this concern, we are proposing to include augmentations to the parent groups to increase parent engagement, which will be based on the work of Mckay, Hoagwood, and colleagues (Mckay, Hibbert, Hoagwood, et al., 2004). We also plan to use the FCU as an alternative platform for delivering the MS
Coping Power. Previous research indicates that the FCU increases parent engagement and leads to reliable reductions in problem behavior in adolescents (Boyd-Ball & Dishion, 2006; Connell, Dishion, et al., 2007; Dishion, Kavanagh, et al., 2002). Further, the families most in need of family intervention services (e.g., single parents, those from high-conflict homes, those with deviant peer involvement) engage more consistently in the FCU. Additionally, engagement and responsiveness to the intervention are similar across racial and ethnic groups and gender (Connell, Dishion, et al., 2007). One potential explanation is that the flexible delivery format and the assessment-driven, collaborative, and tailored nature of the family-centered intervention optimize the engagement of culturally diverse families. In summary, we plan to make developmental adaptations to the standard Coping Power program and implement the model with early adolescents using a group and individual FCU/Tailored version in order to determine which delivery method is associated with the greatest reductions in aggressive behavior problems.

3. PRELIMINARY STUDIES

3.1 JHU CPEI Pilot & Feasibility Study of Coping Power. Over the past 4 years the Indicated Treatments Steering Committee (Drs. Ialongo, Lochman, Reinke, Weist, and Duval-Harvey) from the JHU CPEI have worked to develop an implementation support system and refine the Coping Power Intervention for use in BCPSS elementary schools. Four school-based mental health clinicians from the University of Maryland and Johns Hopkins University received intensive training and ongoing supervision regarding the implementation of Coping Power. The clinicians implemented the Coping Power child and parent groups in the BCPSS elementary schools over the course of 1.5 years with 19 children. Data on group attendance, homework completion, and consumer satisfaction were collected. For the child groups, 83.2% of the students reported that what they learned in the groups was helpful and 82.1% thought that what they talked about as a group was important. Additionally, 86.9% of the children agreed that their group leader did a good job leading the group. Overall 96.7% of the parents felt that the content of the parent sessions was helpful, and 96.7% described the group discussion and interaction as helpful.

Clinicians also completed a Session Debriefing Process Log after each session in order to document revisions made to the session content and activities, difficulties the students had understanding the material, and challenges with time management, engagement and participation. Focus groups and individual clinician interviews were conducted at the completion of all the Coping Power groups. The qualitative data from the individual clinician interviews and focus groups, along with the feedback from the clinician’s weekly session data, was organized into a “Tips for a Successful Coping Power Group.” This manual includes one-page inserts for each child and parent session with revisions to language and examples to make the content more culturally relevant to urban, African-American families. The clinicians reported that many of the children did not have the knowledge and skills that was necessary for Coping Power; therefore, the Tips for a Successful Coping Power Group Manual provides definitions of commonly used vocabulary words and examples to help the students better relate to the session content.

Several additional materials were developed to increase implementation quality and effectiveness, including the following: (1) An intervention Process Manual that includes an extensive training protocol with the necessary details to run a parent and child group. The manual also includes information for how to handle disruptive behavior in groups, parents that monopolize group discussion, group members that do not complete homework, and tips for increasing parent participation; (2) Teacher Training Materials (e.g., PowerPoint presentation and handouts) with the aim of encouraging teachers to prompt and reinforce the skills their students learned in the Coping Power groups; (3) Supplemental Teacher Materials for the child groups providing teachers with a 1-page summary of the skills their students learned in each session and suggestions for how they could help the students generalize skills to the classroom; (4) Supplemental Parent Materials for the child groups providing parents with a one page summary of the skills the child learned in each session and suggestions for how they could help their child generalize the skills at home; and (5) Supplemental Parent Group Parenting Materials intended specifically for parents who attend the parent groups but missed a session. The supplemental parent group materials provide a 1-page summary of the session missed and suggestions for how to implement the strategies at home. The described refinements and enhancements were used last year to train and supervise three new school-based mental health clinicians to implement Coping Power in a second group of schools, with approximately 15 more children. The originally trained clinicians acted as mentors and coaches to the newly trained clinicians.

4. METHODS

4.1 Overview of the Research Design. As part of our Phase 1 efforts in Year 1, we will conduct an extensive review of the literature regarding developmental factors to be addressed during the early adolescent years. We will also hold a “Consensus Conference” which includes a panel of invited experts who will review the developmental and prevention literature relevant to universal, selective, and indicated preventive interventions for students in grades 6-8 (see detailed description in the Operations Core of the current application). We will then conduct two sets
of focus groups with key stakeholders (2 groups held separately for parents, children, teachers, and school-mental health clinicians) regarding the key issues relevant to the development of aggressive, disruptive, and delinquent behavior problems (e.g., substance use, risky sexual behavior, peer deviance) during adolescence. The focus groups will be co-facilitated by Dr. Gittelsohn, the Center’s ethnographer, and Dr. Bradshaw, who has prior experience leading focus groups and summarizing qualitative research. This information, together with Dr. Lochman’s and Boymyer’s input, will result in a series of modified Coping Power lessons that are more developmentally appropriate for adolescents. Drs. Sugai and Dishion will provide consultation regarding the integration of PBIS and the FCU, respectively. Phase 2 activities will be carried out in Year 2, and include the piloting of the MS Coping Power parent and child lessons with approximately 12 children in a single K-8 school, targeting children in grades 6-8 who do not respond adequately to school-wide PBIS. Specifically, Phase 2 will include piloting the standard MS Coping Power (2 groups) and the FCU/Tailored MS Coping Power (4 children), both in combination with PBIS. Both qualitative (via another round of focus groups) and quantitative data will be collected from parents, children, teachers, and clinicians regarding the acceptability, feasibility, and satisfaction with the MS Coping Power and FCU/Tailored Coping Power programs. Phase 3 spans Years 3 & 4, and includes a comparison between the standard MS Coping Power and FCU/Tailored versions versus “care as usual” for approximately 48 children per year in grades 6-8 who are not responding adequately to PBIS in three PBIS K-8 schools (for a total of 96 children). Data will be collected on both implementation quality and pre/post-test assessments of key outcomes (e.g., aggression, delinquency, substance use) and mediators of behavior change among students (e.g., social-cognitive processing) and parents (e.g., monitoring, positive communication). Phase 4 of the project focuses on summarizing the findings from earlier phases through peer-reviewed publications and the preparation of an R01 to test the efficacy of the MS Coping Power with the PBIS and family-engagement augmentations versus the FCU/Tailored Coping Power.

4.2 Description of the Interventions.

**Coping Power.** As described above, Coping Power is an indicated preventive intervention delivered to at-risk children and their parents. The program is based on an empirical model of risk factors for substance use, aggression, and delinquency and addresses key factors including social competence, self-regulation, and positive parental involvement. The program includes a group and individual child component, as well as a group component for parents, and will be adapted for use with children in grades 6-8 and implemented across one school year. The standard program has been primarily used with upper elementary school children and sixth graders.

**PBIS.** As previously described, PBIS is a non-curricular universal prevention strategy that aims to alter the school environment by creating improved systems (e.g., discipline, reinforcement) and procedures (e.g., office referral, reinforcement, training, leadership) that promote positive change in staff and student behaviors. The program draws upon behavioral, social learning, and organizational behavioral principles (Lewis & Sugai, 1999; Sugai & Horner, 2006), which were traditionally used with individual students, and extends and applies them to an entire student body consistently across all school contexts (Durand & Carr, 1992). This whole-school strategy aims to prevent disruptive behavior and enhance the school’s organizational climate by creating and sustaining primary (school-wide), secondary (classroom), and tertiary (individual) systems of support. Over 560 schools in the state of Maryland have been trained in the universal components of PBIS. Consistent with the JHU CPEI’s nested prevention approach, all schools participating in this project will have previously received training in PBIS and implement the program with high fidelity. They will use Coping Power as an indicated prevention program for children not responding adequately to the universal PBIS model.

**Family Checkup (FCU).** The FCU is a tailored, adaptive intervention (see Collins, Murphy, & Bierman, 2004) designed for use within school settings. Based on Miller and Rollnick’s (2002) motivation-based Drinker’s Check-Up, the FCU is an empirically validated intervention that has been used to effectively reduce the growth of problem behavior, enhance parenting skills, reduce family conflict, and reduce the growth of substance use in middle-school youth (Dishion, Kavanagh, et al., 2002; Dishion & Stormshak, 2006). Briefly, the FCU involves three meetings with parents. The clinician facilitates sessions using motivational interviewing strategies for promoting motivation to change (e.g., providing personalized feedback, eliciting and reinforcing change talk, enhancing self-efficacy). The first meeting is an initial interview during which the clinician explores the parents’ goals and concerns as well as their personal motivation for change. The second session involves administration of a brief assessment packet given to the parent, child, and teacher and a videotaped family interaction assessment. The third meeting is a feedback session to discuss the results of the assessment in terms of (a) enhancing motivation to change and (b) identifying a menu of family-based intervention options. The parents and adolescent in collaboration with the clinician then select the intervention options that best fit their needs and interests.

4.3 Phase 1: Overview of the Adaptation Approach. The primary modifications to the standard Coping Power program, originally designed for students transiting to middle school (grades 4-6), will be to ensure it is
developmentally appropriate for early adolescents in grades 6-8. We also intend to promote greater generalization of the skills learned in the MS Coping Power group to non-group school settings (e.g., classroom, cafeteria, hallways) by integrating the content with school-wide PBIS and providing other enhancements to the parent group components, based on the work of Hoagwood and colleagues (Mckay, Hibbert, Hoagwood, et al., 2004). In addition, we aim to test whether an alternative delivery of the MS Coping Power content, in conjunction with the FCU and individually-tailored elements of the Coping Power program, will be associated with greater parental involvement and engagement in the intervention and with differential outcomes. During Year 1, we will conduct the previously mentioned Consensus Conference on developmentally appropriate preventive interventions for middle schoolers. We will also conduct 2 sets of focus groups with parents, teachers, clinicians, and children (for a total of 8 focus groups) to better understand the unique challenges faced by urban early adolescents, in order to make the necessary modifications to the standard Coping Power Program. Below we briefly outline some of the anticipated modifications and enhancements to be made to the standard Coping Power program and the rationale for each. We anticipate making other modifications based on the Consensus Conference and the focus groups.

**Developmental Adaptations.** We will make a series of modifications to the current Coping Power program which are consistent with the contextual social-cognitive framework and an ecological developmental approach (Tolan et al., 1995) to address factors at the individual, family, school, peer group, and cultural level that are appropriate for early adolescents. **Individual-level.** Early adolescence is a time when youth experience multiple physiological, social, emotional, and cognitive changes (Byrnes, 2003). Specifically, sexuality and dynamics related to puberty become more salient at this developmental period, and youth may be distracted as a result by emotions, changes in their bodies, and romantic relationships (Roese, et al., 2000). Early adolescents’ inability to regulate their emotions, especially anger, has been linked to their antisocial behavior, including substance use initiation (Pardini et al., 2004). Therefore, this may be an age group that is more challenging to engage in an intervention. One strategy to improve engagement includes the involvement of peer leadership or program “veterans” to inform the adaptation of the intervention and potentially co-facilitate some of the sessions. The involvement of prosocial peer leadership may create an opportunity to improve the intervention’s responsiveness to developmental stage as well as culturally-specific risk and resilience factors related to aggression. Again, focus groups with young people in this age group will be important in the formative stages of the adaptation to learn from the perspective of youth themselves what kinds of modifications may improve engagement and effectiveness. **Family-level.** Research shows that parent-child conflict peaks from early to mid-adolescence (Laursen, et al., 1998), and that child effects on parents’ poor parenting practices (reduced warmth, weaker monitoring) become more apparent in the middle school period (Fite et al., 2006). Likewise, having someone at home to talk to and to help problem solve has been linked with lower aggression (Byrnes, 2003). Some modifications will be made to accommodate these developmental changes, such as parent sessions that focus on increasing family time and activities. For example, we plan to incorporate a parent session focused on developmental issues and challenges faced during adolescence, and how that may relate to increased conflict. Current sessions on parent monitoring, family problem solving, and planning of family meetings will be expanded and adapted to address common issues of early adolescents. Training on effective conflict resolution strategies will be provided as well. **School-level.** Consistent with the school-wide PBIS model (Sugai & Horner, 2006), recent research by Reis et al. (2007) suggests the following school-wide strategies are effective at reducing proactive aggression in middle schools: macro-school policy and rule setting procedures that are inclusive of student input; adjustments to instructional design to focus on understanding rather than memorization; and adjustments to the instructional content to make it more culturally sensitive. School environments that encourage and facilitate adolescents’ developmental trend towards increasing independence may reduce stress; alternately, those schools that present obstacles to expression of independence may derail normative developmental processes (Eccles & Roese, 2003). **Peer-level.** Research indicates that parental influence begins to decline steeply at this developmental stage (Byrnes, 2003). Shifting from elementary school into the middle school setting also means a larger and more diverse peer group and an increased emphasis on academic achievement (Eccles & Roese, 2003). It is during these years that children’s involvement in deviant peer groups becomes more clearly linked to children’s increase in antisocial behaviors such as substance use (Fite et al., 2007). Because young people’s orientation for approval is shifting from their parents and teachers to their peers during adolescence, some accountability to fulfill goals or other strategies of the Coping Power program may be directed towards the child’s peers. Current Coping Power sessions on conflict management with peers, peer pressure resistance, and enhanced involvement with non-deviant peer groups will be adapted and substantially expanded. **Cultural Level.** Adaptations to the child and parenting component of the program may need to be considered to address how the racial structure of peer groups influence children’s social acceptance (Jackson et al., 2006) and to incorporate racial socialization practices among African American parents. Coard et al. (2004) conducted a qualitative study and found that the primary racial socialization messages delivered by African American parents include racial achievement; preparation for bias;
racial equality; and racial pride. Racial socialization practices are employed by African American parents to promote healthy adjustment despite race-related ecological barriers such as racial discrimination (Lau, 2006). A recent review suggests that racial socialization practices are linked with better emotional, behavioral, and academic outcomes among African American children (Coard et al., 2004). Furthermore, African American children who acquire strong ethnic identity have been found to have lower levels of aggressive behavior; this relation appears to be mediated by children’s development of social goals that are less dominance- and revenge-oriented (Holmes & Lochman, in press). Issues of racial equity, bias, and discrimination may intersect with anger and aggressive behavior in ways that will be considered in the proposed adaptation of Coping Power.

**PBIS Integration.** School-wide PBIS involves defining and teaching clear expectations for behavior in all settings to all students and staff, and rewarding students who exhibit expected pro-social behaviors. PBIS acts to create a safe, consistent, and predictable environment which will allow children to practice and be reinforced for skills learned from the MS Coping Power intervention across school settings. Additionally, MS Coping Power and PBIS language will be made consistent across programs, behavior cards, and student goals devised as part of the MS Coping Power program will be tied to the school-wide behavior expectations. The MS Coping Power clinician, classroom teachers, and other school staff will reward students for exhibiting pro-social behaviors and skills learned from MS Coping Power. The consistent language and rewarding of behaviors across programs will make it more likely that skills and behaviors learned from MS Coping Power will be practiced and reinforced across school settings, thus increasing generalization.

**FCU Integration.** The FCU will be used as a platform for individually tailoring components of the MS Coping Power program to meet the specific needs of children and their families. Following this approach, a set of pre-treatment individual-, peer-, school, and family-level “tailoring variables” (e.g., levels and types of aggression, peer relationships, self-regulation, family environment, behavior management) will be identified and matched with the various components of the MS Coping Power intervention to address specific risk and protective factors. By identifying, a priori, which interventions are likely to be most efficacious for which individuals within certain contexts (based on baseline characteristics), the adaptive or dynamic intervention is hypothesized to optimize treatment effects (Collins et al., 2004; 2005; Murphy, 2006). The FCU/Tailored program will offer the added advantage of allowing us to assess the relative benefit of individual versus group-delivered MS Coping Power. This is a particularly salient issue for interventions involving aggressive middle school students because of the potential for deviant peer contagion (Dishion, Poulin, & Burraston, 2001). We expect to minimize deviant peer contagion in the group-delivered MS program through adaptations discussed above (e.g., strengthening components related to non-deviant peer affiliations) and also through careful clinician training and supervision to provide highly structured sessions without inadvertently reinforcing behaviors. Additionally, we will monitor deviant behaviors in group by videotaping all sessions and coding for deviancy training using Dr. Dishion’s coding system; collecting ongoing assessments from parents, children, and teachers about deviant peer affiliations; and providing frequent supervision and feedback to the clinicians regarding this issue. The FCU/Tailored model will provide us with valuable comparison data to determine the relative effects of the individualized vs. the group-delivered program on important outcomes, including changes in deviant peer affiliations.

An equal number of children will receive the FCU/Tailored version and the standard MS Coping Power. The parents of the children who receive the FCU/Tailored version will attend a three session FCU as described previously. During the third session the family will be given feedback on the assessment-based, tailored variables targeting key risk and protection factors related to the MS Coping Power intervention. The parents and child in collaboration with the clinician will select from the menu of options the specific MS Coping Power components that match the needs of the family. Each family will then complete the identified components individually with the school-based practitioner. For example, families with high levels of parent-child conflict will be offered specific sessions from the MS Coping Power parent component pertaining to family communication and problem solving. By contrast, in the standard MS Coping Power program all parents will be given all components of the parenting program regardless of their levels parent-child conflict.

**Intervention integrity during the adaptation process.** To ensure fidelity to the model during the adaptation process, adherence to the core theoretical principles of Coping Power will inform decisions on each proposed modification. All modifications will be made in close consultation with Dr. Lochman, the developer of the model. In addition, Coping Power was previously evaluated with 6th graders and with upper elementary school children in an efficacy trial (Lochman & Wells, 2004). Clinicians also have been trained to make minor adaptations to the curriculum to make it more appropriate for middle schoolers; however, these adaptations were not formalized or standardized, as is purpose in the current application. Nevertheless, these experiences will assist with the proposed adaptation of Coping Power further into the early adolescent developmental period.
4.4 Phase 2: Pilot in 1 BCPSS K-8 PBIS School. In Year 2, we will pilot the MS Coping Power program in one BCPSS K-8 school, which was previously trained in PBIS by the state-wide PBIS Maryland Initiative. Two MS Coping Power groups of approximately 4 children each will be conducted, for a total of 8 children and 8 parents. Additionally, the FCU/Tailored intervention will be given to another 4 children and their parents. In total, the pilot will include approximately 12 children. The children will be selected for participation in the MS Coping Power group or FCU/Tailored program will be based “non-responses” to PBIS, as operationalized as four or more Office Disciplinary Referrals (ODRs) in the previous school year. The non-responders will be identified for further screening by their teachers, who will complete an enhanced version of the TOCA-R (Koth et al., under review), via the web-based INSPIRE program. Children scoring above the cut-off score on the aggressive/disruptive behavior scale will be considered for inclusion in the pilot. Children eligible for participation in the project will provide parental consent and youth assent. Clinicians will receive training on MS Coping Power, PBIS, and FCU as described below. Concurrent with the piloting of the MS Coping Power and FCU/Tailored program, a second round of 8 focus groups (2 with each parents, teachers, children, clinicians) will be conducted by Drs. Gittlesohn and Bradshaw to make additional modifications to the content and delivery of the interventions. Quantitative feasibility, acceptability, and satisfaction data will be collected from participating children, parents, teachers, and clinicians via self-report rating scales.

4.5 Phase 3: Feasibility & Acceptability Study in 3 BCPSS K-8 PBIS Schools. In Years 3-4, we will test the feasibility and acceptability of the program in 3 K-8 BCPSS schools previously trained in PBIS by the state-wide PBIS Maryland Initiative. Each year, approximately 48 children (16 per school) will be identified based on the selection criteria described above, as being eligible for participation in the project (total of 96 child/parent dyads across Years 3-4). One-third of the eligible and (parental) consenting children in each school will be randomly assigned to receive the MS Coping Power program (n=32 total), one-third to receive the FCU/Tailored program (n=32), and one-third to receive care as usual (n=32). All clinicians will receive training and supervision (see below) and implement the MS Coping Power and/or FCU/Tailored programs. All children and parents will provide pre- and post-intervention data on a series of child-, parent-, and teacher-reported outcomes and mediators (see below) and implement the adaptations made to the MS Coping Power program. Similarly, the training and intervention protocols and
manuals will be precisely delineated and codified, thereby standardizing the content of each training and intervention contact. In addition, clinicians will have a number of materials available designed to foster correct execution of the interventions, including detailed outlines and checklists that prescribe the necessary materials for each intervention contact, the specific themes or tasks that need to be covered, and related information. Five indicators of implementation quality will be obtained, including the number of sessions scheduled and percentage of objectives completed (both indicators of program delivery). The quality of engagement of clinicians with children and with parents, based on research assistant coding, and number and type of contacts between trainers and clinicians (an indicator of training delivery) will also be tracked. In terms of methods and measures of implementation and participation for the group sessions, clinicians will be required to provide documentation of each contact with parents and children, including, where appropriate, summaries of what transpires, any unique features, duration of the contacts, parent or child attendance, and level of participation and compliance with "homework assignments". Parents and children will report on their implementation and the usefulness of the techniques taught, and will be asked to report on the clinicians' interpersonal and teaching skills. The videotaped observations of child small group and individual sessions will be made to assess the level of skill that the clinicians displayed in administering the intervention, monitor deviant peer contagion processes, and determine the extent to which the intervention protocols were being adhered to as designed. Drs. Lochman and/or Boxmeyer will code a random sample of 25% of the tapes using the Quality of Counselor Engagement and Delivery and the Objectives List for Coping Power Sessions to assess implementation quality and program delivery (see Appendix PRC4). The percentage of objectives completed will indicate dosage. The coders will use the Quality of Counselor Engagement and Delivery measures to rate 14 items related to the clinicians' behavior in the children's group sessions (e.g., tone was warm and positive; makes teaching moments; reinforces prosocial behavior; provides consequences for not following the group rules; lesson proceeds in an orderly way) using a 5-point scale. A similar set of 11 items are used to rate the clinician's behavior during the parent group sessions. Data from Lochman et al.'s school-based field trial indicated a high level of inter-rater agreement using this measure (kappa=.80), and that the parent (α = .82) and child measures (α = .86) had adequate internal consistency. Other measures used to ensure high quality implementation include the Child Group Tracking Form, the Parent Group Tracking Form, and the Child Individual Meeting Tracking Form. These forms record attendance, completion of homework assignments, and level of participation in session activities. Supervisors will review these checklists at their weekly supervision sessions. See Appendix PRC4 for copies of these measures.

**PBIS.** As described above, the School-wide Evaluation Tool (SET; Sugai et al., 2001) will be administered annually in the participating schools to ensure high quality implementation of school-wide PBIS for the duration of the pilots. Additional support and technical assistance regarding the PBIS program will be provided through the district's PBIS "coach" to ensure consistently high levels of PBIS implementation.

**FCU.** We will follow the procedures developed by Dishion and his colleagues to ensure fidelity to the FCU (Dishion & Stormshak, 2007). Specifically, we will monitor adherence to the primary components of each FCU session (interview, assessment, and feedback) using observational coding of videotapes. Each clinician will videotape each FCU session. Drs. Reinke and Herman will code these tapes for critical variables indicating FCU implementation including clinician warmth, clinician-participant rapport, and behavioral signs of participant motivation (e.g., asking questions, nodding, using commitment and change talk). Dr. Dishion will supervise these activities.

### 4.7 Measures of Intervention Outcomes

The following measures will be administered to all 96 children (32 MS Coping, 32 FCU/Tailored, and 32 control), prior to randomization and at the end of the year-long trial. The **Home Inventory with Child** (HIWC; Dodge, Bates, & Pettit, 1990) will be used to assess children's deviant perceptions of hostility in others. The HIWC presents children with vignettes in which protagonist children either enter a peer group unsuccessfully or receive minor harm (e.g., being bumped). The percentage of hostile attributions children make in response to these questions consistently predicts children's levels of aggression (Crick & Dodge, 1994; Dodge et al., 1995; Dodge & Price, 1994). The **Problem-Solving Measure for Conflict** (Lochman & Lampron, 1986) will assess children's abilities to solve social problems. Students will report their association with deviant peers in response to a 16-item scale taken from the JHU CPEI Youth Interview (Chilcoat & Anthony, 1996; Chilcoat et al., 1995), which measures friends' use of drugs, friends' involvement in other delinquent behaviors, etc. Teachers will complete an expanded version of the TOCA-R administered via the INSPIRE program. This expanded TOCA-R includes items regarding aggressive/disruptive behavior and concentration problems, emotion regulation problems, internalizing symptoms, prosocial behavior, parental involvement, and family stability. This expanded version of the TOCA-R was tested by Drs. Leaf and Bradshaw in both PBIS trials and has been shown to have high internal consistency and test-retest reliability (Koth et al., under review). Academic records (e.g., attendance, office referrals, suspensions, academic performance) will also be obtained to examine the impact of the programs.

Parents will provide assessments of parenting behaviors, parent-child relations, and child social relations. The **Parental Monitoring Interview** (Dishion et al., 1991) will be used to assess monitoring of and involvement in
children’s activities, consistency of discipline, and family rules. Parental involvement in their child’s school will be assessed using the Parent-Teacher Involvement Questionnaire (parent version) (CPPRG, 1991), a 21-item measure (α = .91) that assesses both the teacher’s and parent’s perceptions of parent involvement in children’s education, and that was developed for the Fast Track Project. Emotions as a Child Questionnaire (ECQ, Klimes-Dougan et al., 2001; Magai, 1997) will assess factors of magnification and punitiveness, for which internal consistencies have been found to be satisfactory (α > .70 for both factors) for low-income, ethnically diverse samples of school-age children (Shaw et al., 2006). More global assessments of parent–child relationship quality will be evaluated using two factors from the Adult–Child Relationship Scale (Pianta & Steinberg, 1991). These factors include conflict and warmth, from which a composite of parent–child relationship quality has been generated in past research with Dishion’s Early Steps pilot sample. Finally, both parents and teachers will provide information on the child’s social relations and peer affiliations. Both will complete the Social Skills Rating Scale (Gresham & Elliott, 1990), a 38-item survey that includes factors assessing cooperation, assertion, responsibility, empathy, self-control, and academic competence. In addition to videotape observation coding of deviant peer behaviors during MS Coping Power group sessions, we will use the Parent and Teacher Rating of Peers and Social Skills (TPRSK and PPRSK), which assess the child’s affiliation with prosocial and deviant peers at home or at school (Dishion & Kavanagh, 2003).

4.8 Phase 4: Disseminate Findings & Develop R01 Efficacy Trial. In Year 5 of the proposed application, we intend to summarize the findings from the pilot in a series of manuscripts which will be submitted for peer-review and presentations at professional conferences. Findings from the project will also be disseminated locally through presentations at the BCPSS and PBIS Maryland State Leadership Team, of which Dr. Bradshaw is a member. The findings from the pilot will be used to calculate the sample size needed to power the proposed trial. We will also prepare and submit an R01 application to NIMH to conduct a larger scale efficacy trial of the MS version of Coping Power using the delivery model which the pilot indicates has the greatest impact. In conclusion, the proposed study has the potential to address a significant gap in the extant research related to the paucity of evidence-based preventive intervention for early adolescents displaying symptoms of aggressive and disruptive behavior problems.

5. DATA ANALYSIS

5.1. Analytic Approach. We will examine the feasibility and acceptability data collected in Years 2-3 using descriptive analyses on the participant surveys and self-report satisfaction and feedback measures. The qualitative data will be summarized for development purposes. Common themes will be identified and grouped, and used to guide the development and refinement processes. In Years 2-4, we will examine the implementation quality of the MS Coping Power, FCU/Tailored program, and PBIS interventions by conducting descriptive analyses on the fidelity measures (e.g., Quality of Counselor Engagement and Delivery, Objectives List for Coping Power Sessions, FCU videotape coding, SET) in order to identify potential elements of the models which were poorly implemented, and provide support to the clinicians and schools accordingly. To examine the preliminary outcomes associated with implementation of the adapted programs in Years 3-4, we will calculate Cohen’s d effect sizes associated with the MS Coping Power and FCU/Tailored program relative to the Usual Care condition for each targeted outcome variable (e.g., child aggressive behaviors, parenting behaviors, social relations, social-cognitive processing). Additionally, we will conduct repeated measures multivariate analysis of variance (MANOVA) with each of the dependent measures to determine the impact of the Coping Power program on student and parent outcomes. An overall test will be conducted on each outcome within a particular domain (e.g., deviant peers, social-cognitive-processing), then if significant, the univariate tests will be examined. We will also explore if there are significant baseline differences between the children randomized to the treatment and control conditions, and adjust accordingly using analysis of covariance (ANCOVA). Although the relatively small sample size limits our power to detect significant interaction effects, we will explore select potential moderated effects, such as differences by gender. We will also explore possible variation in outcomes among the treated children by fidelity and/or dosage ratings, such as level of parent participation or attendance at child and/or parent sessions. All analyses will adjust for the clustering of children within schools and groups.

5. Human Subjects

5.1 Creation of a Data Safety and Monitoring Board. The Center Principal Investigator, Dr. Nick Ialongo, has the overall responsibility for monitoring data and safety issues. Because many of the studies proposed within the center are to determine feasibility and/or obtain pilot data, the necessity for independent data and safety monitoring board members will depend on the nature of the specific project and the risk /benefit ratio of the particular study. The Data and Safety Monitoring Committee will be headed by the Center’s Research Ethicist, Dr. Holly Taylor, and will include as members, the Center Director and Deputy Directors (Drs. Ialongo and Bradshaw and
Leaf), the Center Intervention Coordinator (a Ph.D. level School Psychologist to be hired by the Baltimore City Public Schools with Center funds), the Director of the Baltimore City Public Schools Office of Research, Evaluation, and Accountability (Dr. Feldman), a representative from the Baltimore City Public School System’s legal office, and members of the Center’s Community Advisory Board (including a parent and youth). The committee will meet to review each of the pilot intervention and assessment initiatives and consider the risk/benefits ratio, precautions to minimize risk, the plan for crisis response, the disclosure and consent process, steps taken to insure confidentiality, and the process for documenting and reporting events to the JHU Bloomberg School of Public Health Committee on Human Research and our NIMH Project Officer. The proposed approach to each of these issues is described below. Depending on the nature of the risk/benefit ratio, the committee will consider and recommend whether a smaller internal (to the Center) data and safety monitoring group will be tasked to review specific initiatives through their inception and completion, or whether a monitoring board that includes experts independent to the Center would be preferable. The NIMH project officer for the Center and the JHU Committee on Human Research will be consulted in this decision. If in fact independent members are deemed necessary by the JHU SPH IRB and our NIMH program officer, we will seek out school mental health professionals and research evaluation members from the surrounding school districts (including the Baltimore, Anne Arundel and Howard County school districts) to chair and serve as members of the board. We will ask these members to develop a charter that will be approved by our NIMH program officer and the JHU IRB Committee on Human Research.

5.2 Characteristics of the Study Participants.

The study participants will include the K-8 students participating in the pilot intervention and assessment feasibility studies, along with their parents, teachers, and school-based mental health clinicians. In terms of ethnic make-up, the participants will be representative of Baltimore City, which is predominately African-American. We assume that we will have equal numbers of boys and girls.

5.3 Risks/Benefits and Steps Taken to Reduce Risks and Respond to Participants in Distress and/or Imminent Danger

Risks. For the most part, the data gathering requirements of the proposed research initiatives pose no more than minimal risk to the participants. Our confidence in terms of the measures to be used is based on our 23 years of experience in using virtually all of these instruments and our continued policy of piloting all new measures and revisions. Moreover, participants have reported a high level of comfort with the assessments in the past. Indeed, we have had no reports from participants of deleterious side effects. However, with respect to some data (e.g. psychological assessments), possible inadvertent disclosure of the data is a concern, as is possible stressful effects of the assessment procedures. To protect against the risk of inadvertent disclosure, interviewers receive extensive training in the need for confidentiality and the practices, which will insure confidentiality is not broken. Interviewers will also receive extensive training in dealing with participants who become distressed during the interview. Relatedly, in the case of a participant (teacher, child or parent) who requests mental health services or is identified by an interviewer as in severe distress during or soon after the time of assessment, the PI, a clinical psychologist, will make a determination of the need for services and the nature of the services needed based on a review of the existing data, including the participant's and interviewer's report. An appropriate referral will then be made if necessary and the study’s assessment coordinator will then facilitate the necessary links to services for the participant.

Potential Benefits. In terms of our universal intervention initiatives, the proposed research should enhance our understanding of the significance of improved teacher behavior management and socioemotional development on children’s behavior, mental health, and educational success. In terms of our indicated intervention initiatives, we should better understand their feasibility and acceptability and their potential impact on antisocial behavior and depression. The assessments of the intervention outcomes may also facilitate the development of screening measures, which could be administered to large populations of children in hopes of identifying children in need of mental health services. During the course of the study, we may also be able to identify participants experiencing significant distress and make appropriate referrals for treatment. These immediate benefits may also be linked to later decreases in the risk of later drug use, conduct disorder and psychiatric distress for participants.

5.4 Disclosure/Consent Processes. Permission for participation will be obtained from intervention condition teachers for the study of factors influencing implementation in PRC Initiative 1 (GBG+PATHS+PBIS+CCU
Integration) and the parents/guardians of participating children in the form of written informed consent for PRC Initiatives 1, 3 (Middle School Depression Prevention Intervention), and 4 (Coping Power Adaptation). The youth surveys, teacher ratings and school record searches included in PRC Initiative 2 will not involve identifiers other than gender, grade and school. Verbal assent will be obtained from children. Letters will be sent by mail to intervention condition teachers in PRC Initiative 1 and to all parents of children in PRC Initiatives 1, 3 and 4 explaining the study with a signature form requesting that the intervention teachers and parents, respectively give consent, withhold it, or ask for more information. Follow-up calls will be made to all potential consenting adults, including those who request more information and those who have not responded; visits to the classroom in the case of intervention teachers and to the home for parents will be made by research staff when necessary. Originals of the written consent forms from each intervention teacher and all parents will stored in locked files. Teachers and parents will be given a written explanation in the consent form of the exceptions to confidentiality. That is, we will only break confidentiality in the event of evidence of child abuse or a report and/or an observation that suggests the teacher, parent, or the child or some other person is in imminent danger of harm. Teachers and parents are also informed verbally and in writing that they have the right to refuse participation or drop out of the study at any time and that their decision not to participate in the research will have no adverse consequences.

5.5 Confidentiality Assurances

We treat all the study data as sensitive and confidential, removing personal identifiers from computer and hard copy forms and maintaining a separate master list under high security. All data is stored in locked file cabinets, with access limited to data management staff only. All participating teachers and parents are informed that all data are confidential and that we cannot disclose the results of any individual participant's assessments. Participants are informed of the exceptions to this general rule. That is, we will only break confidentiality in the event of evidence of child abuse or a report and/or observation that suggests the teacher, parent or the child or some other person is in imminent danger of harm. The location of the stored data is in Suite 901 in the Candler Bldg, 111 Market Place, Baltimore, MD 21202. The person responsible for the storage of the data is the P.I, Nick Ialongo (tel.# 410-347-3221). Regarding the disposition of the data at the completion of the study, any hard copy forms will be destroyed leaving only an electronic data base, with no identifying information other than a coded identification number.

5.6 Documenting and Reporting Events to the IRB, Including Notifying the NIMH Project Officer of IRB Decisions about Events

Regarding the procedures for reporting adverse events, we follow the procedures as outlined by the Johns Hopkins Bloomberg School of Public Health Internal Review Board, which are consistent with the guidelines given by the OHRP. A written report of all adverse events is submitted to the IRB immediately following the event. The event description is reviewed by the IRB staff and the PI is then instructed by the IRB as to what action needs to taken to deal with the event. The NIDA program officer will be sent a copy of the adverse event report form along with the action taken.

5.7 Women and Minorities. We will assume that we will have equal number of boys and girls and the ethnic make-up will reflect that of the BCPSS.

7. Vertebrate Animals

N/A

8. References


Ialongo, Nicholas


See Operations Core.

9. Consultants/Letters of Support

See Operations Core.