

**CENTER FOR PREVENTION AND EARLY INTERVENTION**  
**Center Overview**

**1. OVERALL SPECIFIC AIMS**

This application seeks support for an Advanced Center for Intervention and Services Research (ACISR), the Johns Hopkins Center for Prevention and Early Intervention (JHU CPEI). The mission of the Center is to carry out methodological and pilot and feasibility research to support the submission of RO1 funded evaluations of the effectiveness of evidence-based preventive and early interventions aimed at the reduction of aggressive/disruptive behavior in elementary and middle school youth. The distal targets of these interventions are antisocial behavior, depression, and substance abuse in adolescence and adulthood. The Center will continue to employ an integrated approach to prevention wherein indicated interventions are nested within a framework of universal preventive interventions. The **goal** of the JHU CPEI is *to reduce the incidence and prevalence of mental and behavioral disorders among children and youth and their associated impairments by conducting research and training that aids local school systems and communities (1) in creating safe and supportive learning environments for all students and (2) seamlessly linking children and youth not responding to universal interventions with indicated preventive interventions*. The Center builds on the earlier and ongoing work of our current ACISR and a more than two decade long academic/community partnership with the Baltimore City Public School System (BCPSS) and mental health service providers in Baltimore City.

Epidemiologic research indicates that the majority of individuals ever having a mental disorder will first experience this disorder during childhood or adolescence (Kellam et al., 2008; Kessler et al. 2005; Schaeffer et al., 2003; 2006). The **rationale** for the proposed activities is that although there is mounting evidence of the efficacy of both *prevention (Kellam et al., 2008; Ialongo et al., 2001) and early interventions* (for reviews see Berryhill & Prinz, 2003; Burns et al., 2002; Catalano et al., 2002; Greenberg et al, 2001; Hahn et al., 2007), *the results actually being observed in the community and in local school systems differ greatly from those achieved in these efficacy research studies (Domitrovich et al., in press, Overview Appendix)*. The need for an increased research capacity to address this problem is described in the NIMH Draft Strategic Plan (2007), National Advisory Mental Health Council's Services Research and Clinical Epidemiology Workgroup (2006), the President's New Freedom Commission on Mental Health (2003), and the Institute of Medicine's (2006) *Crossing the Quality Chasm* reports. In order to achieve our goal of reducing the *incidence and prevalence of mental and behavioral disorders among children and youth and their associated impairment*, the Center supports and integrates the efforts of researchers at the Johns Hopkins University and researchers working at universities across the country to collaboratively pilot, implement, evaluate, and disseminate research and research training that has the potential of reducing the incidence and prevalence of mental and behavioral disorders and their associated impairments.

Consistent with the above, ***the proposed JHU CPEI's overall specific aims are as follows:***

- Aim 1:** Establish the infrastructure necessary for administration, data management, analysis, and dissemination of the products of the Principal Research and Methods Cores;
- Aim 2:** Support efforts to improve the design, implementation, and analysis of school-based effectiveness studies through advances in statistical and economic methods development;
- Aim 3:** Support the piloting and feasibility testing of the integration of promising and/or efficacious preventive and early interventions designed to reduce early aggressive behavior and its distal correlates (antisocial behavior, depression, and substance abuse) in adolescence and adulthood;
- Aim 4:** Support dissemination of the knowledge gained in each of the above areas in order to improve prevention and early intervention research and the capacity of prevention and intervention researchers.

**2. BACKGROUND AND SIGNIFICANCE**

**Recent research indicating that the first onset of mental disorders commonly occurs in childhood or adolescence (e.g., Kessler et al. 2005) supports the need for prevention and early intervention efforts.**

Aggression in first grade has been shown to predict subsequent mental disorders, substance abuse, and school disruptions (Kellam et al., 2008; Petras et al., 2008; Schaeffer et al., 2003, 2006). Given the recurrent nature or persistence of mental disorders, children and adolescents who experience an episode are more likely to experience other episodes in adulthood (Lewinsohn et al., 1999; Rao et al., 1999; Weissman et al., 1999). Researchers have identified numerous early risk and protective factors for psychiatric and substance use disorders (e.g., Hawkins,

Catalano & Miller, 1992; Huston et al., 1994; Ialongo, Edelsohn, & Kellam, 2001; Lochman, Boxmeyer, et al., 2006;). There is considerable evidence from carefully controlled preventive intervention trials that such risk and protective factors and processes are modifiable (Furr-Holden et al., 2004; Ialongo et al., 2001; Kellam et al., 2008; Petras et al., 2008; Storr et al., 2002; Wilcox et al., 2008). Moreover, the risk of later psychiatric symptoms and disorders can be reduced by preventive interventions that target these risk and protective factors and processes (Ialongo et al., 2001; Kellam et al., 2008; Petras et al., 2008; Wilcox et al., 2008). Likewise the existence of effective treatments can reduce the risk of subsequent disorders and reduce the dysfunction related to disorders (Dusenbury et al., 1997; Greenfield & Shore, 1995; Hall & Zigler, 1997; Kazdin & Weisz, 1998). Federal agencies have encouraged the adoption of evidence-based intervention programs by publishing short lists of recommended programs. Although most of the recommended programs have been evaluated within the context of randomized controlled efficacy trials, few studies have examined effects of these interventions as implemented in actual practice settings by the existing providers within those settings (Domitrovich et al., in press; Hoagwood & Johnson, 2003; Hohman & Shear, 2002; Ringheisen et al., 2003; Weisz & Weersing, 1999).

**A recent SAMHSA report to Congress (SAMHSA, 2007) highlighted both the promise of school-based interventions to improve mental health and the need for more research and services.** Public schools in the US graduate only about 70% of their students (Swanson, 2004), with many urban school systems graduating 60% or fewer and the Baltimore City Public Schools System graduating only about 36% of its students (Maryland Report Card, 2006). Early-onset of mental disorders predicts early termination of schooling, particularly failure to graduate high school (Breslau et al., 2008). Successful prevention and early intervention efforts in school settings could not only reduce the occurrence of such mental and behavioral disorders, but the associated impairments in educational and occupational attainment as well.

**Yet the prevention and early interventions most used in schools and targeted at elementary or middle school students differ greatly from those interventions found in the published literature** (National Advisory Mental Health Council's Services Research and Clinical Epidemiology Workgroup, 2006; President's New Freedom Commission on Mental Health, 2003). Although schools are increasingly being utilized as sites for prevention and early interventions, research on the applicability and effectiveness of mental health-focused interventions in schools--especially middle schools--remains scarce. Emerging evidence suggests that school-based interventions can have beneficial effects in promoting positive adolescent mental health (Gillham et al., 2007; Neil & Christensen, 2007). Assessments conducted by our Center and others demonstrated the benefits of early school-based interventions (Greenberg et al., 2001; Ialongo et al., 2006; Kellam et al., 2008; Petras et al., 2008). However, even where research exists, too few studies have included African-American children or children from low-income areas. As described in the Principal Research Core, we are proposing to address these gaps by extending our pre-K to 5 preventive intervention efforts into the middle school years and to continue focusing on economically disadvantaged, urban, African-American youth. We will also continue to focus on linking our indicated and universal preventive interventions to address the needs of children and youth who do not respond to our universal interventions.

**If the U.S. is going to achieve its health objectives for the year 2020, researchers will need more effective strategies for evaluating the functioning of preventive interventions once they are widely disseminated.** Over the past two decades, researchers have developed a number of strategies for testing the efficacy of preventive and early interventions among youth. Moreover, the federal government maintains searchable online registries of mental health and substance abuse interventions that have been reviewed and rated by independent reviewers, (e.g., the National Registry of Evidence-based Programs and Practices, SAMHSA, 2008). However, there frequently is a substantial gap between the outcomes produced in carefully controlled and monitored efficacy studies and the outcomes achieved by implementers in community settings (Domitrovich et al., in press; Hoagwood & Johnson, 2003; Hohman & Shear, 2002; Ringheisen et al., 2003; Weisz & Weersing, 1999). Unfortunately, studies of the effectiveness and sustainability of preventive interventions have been few and lag considerably behind the sophistication of efficacy trials. Indeed, few effectiveness studies are available for inclusion in the data bases of "effective practices." It is this gap that the Center intends to close.

**Over the past decade, many new statistical techniques have been developed with potential relevance for prevention research.** Policymakers and administrators need ways of determining whether the results seen in randomized trial samples are likely to generalize to target populations (Aos et al., 2004). Even effectiveness trials rarely are done using subjects that are fully representative of the target populations in which the interventions being evaluated may eventually be implemented (Rothwell, 2005). Statistical methods to assess the generalizability of results from effectiveness trials to those target populations are needed (NIMH, 1999; Institute of Medicine, 2006). Collaborations among methodologists from different disciplines and perspectives will be facilitated by the research initiatives described in our Methods Research Core and through dissemination and training activities summarized in our Operations Core. These efforts will facilitate interactions among our affiliated researchers and involve students, fellows, and junior faculty and build on the earlier efforts of Center researchers (e.g., Frangakis & Rubin, 2002; Jo 2008a; Rubin & Stuart, 2006; Stuart 2007b). By address issues of internal and external validity and extending the

“target efficiency” methods developed by Center faculty (e.g., Salkever et al., 2008), we hope to target preventive interventions so that they reach those individuals whom they will most benefit. The research initiatives, along with the training and dissemination activities, will include both methodology experts and other researchers and practitioners in order to promote methodologic and substantive research advances.

**This proposal describes a Center using the knowledge gained in creating and testing epidemiologically-based intervention trials to develop our nation’s capacity to improve the health of populations through the conduct of effectiveness research.** The NIMH Draft Strategic Plan (2007), the National Advisory Mental Health Council’s Services Research and Clinical Epidemiology Workgroup (2006), President’s New Freedom Commission on Mental Health (2003), and Institute of Medicine’s (2001) *Crossing the Quality Chasm* reports all identify a significant lack of research concerning the effectiveness of programs once they are widely disseminated and a lack of knowledge of factors related to sustaining prevention programs at a high level of effectiveness. Researchers here at JHU (e.g., Ialongo et al., 2001; Kellam et al., 2008; Petras et al., 2008) have identified malleable antecedents of mental disorders and have been able to successfully reduce the incidence of these disorders via preventive interventions targeting these early antecedents. We are proposing to work with intervention researchers at the University of Alabama (Drs. Lochman & Boxmeyer), Pennsylvania State University (Drs. Greenberg & Domitrovich), University of Oregon (Dr. Dishion), and Columbia University (Dr. Hoagwood) to design studies aimed at determining how well these programs function when widely disseminated and identify subpopulations who may benefit most from these programs. We also seek to determine why some programs are sustained at a high level of effectiveness and others are not. Factors that may limit the fidelity and/or dosage obtained when interventions are utilized in real world settings are described in greater detail in our Principal Research Core as are the strategies to be developed and tested by the Center for target these factors. For example, prior research indicates that teacher implementation of preventive intervention protocols and student and parent engagement/participation are critical components of successful outcomes (e.g., Boyd-Ball & Dishion, 2006; Connell, Dishion, et al., 2007; Wells, Lochman, & Lenhart, 2008). Consequently, our Operations and Principal Research Cores are requesting funds to facilitate planning and collaborative projects to specifically address issues related to engagement of teachers, school administrators, parents, and students.

**Adopting a public health approach for organizing preventive and early intervention services.** Consistent with a public health perspective, our preventive and early intervention efforts are nested in a public health/human services system (Ialongo, Kellam et al., 2000). At the first level, universal interventions (Mrazek & Haggerty, 1994) are applied to all children and families. At the second level, indicated interventions back up the universal interventions for those children who require more help. Treatment interventions are at the third level and are for those children and families who fail to benefit from the preventive interventions and who have mental disorders. The first or universal level addresses the socialization structure and processes by which public institutions such as schools foster child social, cognitive, emotional, and behavioral development. The settings for universal interventions include the institutions of family, the public school system, and the myriad agencies providing mental health and social services to children and their families. Response to the universal interventions serves as a means of reliably identifying children and families in need of additional and more intensive intervention at either the indicated or treatment level. The third level, treatment services, typically involves the provision of highly specialized habilitative or rehabilitative care within traditional mental health treatment settings. An important advantage of this public health perspective is that the testing and diffusion of effective programs is facilitated by partnerships fostered with the major institutions charged with the public’s health, education, and welfare. Intentionally, we seek to ensure that once the research funds are no longer available, the institution retains a trained cadre of interveners with the materials and protocols necessary to sustain effective programs.

**Expanding the portfolio of our interventions and guiding conceptual framework.** Over the last 4 years, we have expanded our portfolio of universal interventions designed to prevent antisocial behavior, substance use, and anxiety and depression. This expansion prompted us to broaden our conceptual model of these common mental health problems to include key principles from social cognitive learning theory and theories of social-cognitive and emotional development. These enhancements to our conceptual framework are consistent with our new intervention initiatives, which are aimed at facilitating the development of self-regulatory skills as a means of preventing and treating antisocial behavior, substance use, anxiety, and depression. Four primary research initiatives are proposed which aim to integrate universal and indicated preventive interventions and extend them into the middle school years. For example, one initiative includes the combination of PATHS (Promoting Alternative Thinking Strategies), a classroom-based universal preventive intervention targeting social problem solving and emotional intelligence (Greenberg et al., 1995), with the Good Behavior Game (Barrish et al., 1969), a social learning-based classroom intervention fielded in the first and second generation of the JHU Preventive Intervention Research Center universal preventive intervention trials, along with the school-wide Positive Behavioral Interventions and Supports (PBIS, Sugai & Horner, 2002) model, and enhancements to promote high implementation quality. A second initiative nests

indicated developed by Drs. Lochman and Dishion into the school-wide PBIS model, with enhancements to increase generalizability and parent engagement based on Dr. Hoagwood's work on parent empowerment.

**In addition to developing and testing strategies to reduce the prevalence and impairment associated with mental and behavioral disorders, the Center also seeks to meet the Surgeon General's challenge for research on the mental health needs of ethnic minority populations.** The populations for the Center's intervention initiatives include the predominantly African-American, economically disadvantaged children and families long neglected by mental health researchers. As highlighted by the National Advisory Mental Health Council's Services Research and Clinical Epidemiology Workgroup (2006), the President's New Freedom Commission on Mental Health (2003), and the Surgeon General's report on ethnic disparities in mental health (U.S. DHHS, 2001), and recent reports by NIMH (e.g., National Advisory Mental Health Council's Services Research and Clinical Epidemiology Workgroup, 2006), such populations need to be included in research if the U.S. is to achieve its goals of reducing mental and behavioral disorders and reducing racial and ethnic disparities that exist in the use and outcomes of prevention and treatment interventions. The proposed research initiatives will form a major component of the school and mental health service systems' efforts to prevent and treat mental and behavioral disorders in Baltimore (see letters of support from BCPSS CEO and President, Baltimore Mental Health Systems)

**The Center will continue to focus on increasing the number of ethnic minority researchers in prevention and early intervention research.** Nearly 12 years ago, Drs. Leaf and Ialongo developed a collaboration with Dr. Warren Rhodes, then Chair of the Psychology Department at Morgan State University (a historically Black college), around the provision of didactic and field work experiences to Morgan State undergraduates interested in careers in prevention science. Morgan State University was subsequently funded through the R25 mechanism to sustain and expand that collaboration and many of the students in this collaboration have gone onto medical school and graduate work in psychology, social work, and nursing (See Overview Appendix). Our current ACISR covered the tuition costs for the Morgan State R25 trainees to attend our JHU Department of Mental Health's Summer Institute courses on prevention science; design and analysis of group randomized trials; longitudinal analysis with latent variables; and estimating the effects of mental health interventions in non-experimental settings. Drs. Bradshaw, Ialongo, and Leaf have served as mentors for 6 trainees from the CDC-funded Research Initiatives for Student Enhancement (RISE) training grant, which is directed by Dr. Harolyn Belcher (former K-Award Mentee of Dr. Ialongo's) and is focused on supporting minority graduate and undergraduate students interested in obtaining additional training in public health research. Drs. Bradshaw, Ialongo, and Leaf will continue to serve as mentors for the RISE training program. In addition, nearly 25 of Drs. Ialongo and Leaf's mentees have been from racial or ethnic minority groups. This includes their K-Award and NIMH funded Child Intervention, Prevention and Services training program mentees (CHIPS), along with their postdoctoral fellows from the JHU Kellogg Community Scholars postdoctoral training program, and their NIMH funded prevention and child and adolescent mental health service and system training grants. These efforts and their continuations are described in the Operations Core.

**Overview Of Center Cores.** The efforts of the JHU CPEI are organized within 3 administrative cores: Operations, Research Methods, and Principal Research. The aims of these Cores are summarized below:

**Operations Core (OC).** (Core Director: Ialongo; Core Co-Director: Leaf; Core Members: Bandeen-Roche, Bradshaw, Brice, Eaton, Feldman, Plapinger, Gittlesohn, Taylor, Weist). The OC provides scientific leadership and guidance and supportive services and functions necessary for the Center's Research Methods and Principal Research Cores, and the BCPSS to achieve their aims. The specific aims of the OC are to:

- Aim 1:** Establish the infrastructure necessary for administration, data management, analysis, and dissemination;
- Aim 2:** Support efforts to improve the design, implementation, and analysis of school-based, effectiveness studies through advances in statistical and economic methods development;
- Aim 3:** Support the conduct of pilot, feasibility, and rigorous trials of the integration of promising and/or efficacious preventive and early interventions designed to reduce early aggressive behavior and its distal correlates (antisocial behavior, depression, and substance abuse) in adolescence and adulthood;
- Aim 4:** Support dissemination of the knowledge gained in each of the above areas in order to improve prevention and early intervention research and the capacity of prevention and intervention researchers.

**Research Methods Core (RMC)**. (Core Director: Bandeen-Roche; Core Co-Director: Ialongo; Core Members: Alexandre, Bradshaw, Frangakis, Jo, Leaf, Salkever, Scharfstein, Slade, & Stuart). To support the Center in achieving its mission, the RMC will:

- Aim 1:** Apply and extend innovative statistical methods to assist with the design and analysis of randomized trials, in particular to 1) develop and extend study designs and methods to minimize the effects of attrition of study subjects on study results; 2) develop and extend study designs and methods to handle post-randomization variables such as compliance behavior and mediators in longitudinal evaluations, and 3) develop and extend study designs and methods to assess the generalizability of randomized trial results.
- Aim 2:** Apply and extend innovative economic models to 1) compare alternative statistical/econometric procedures that test for differences between distal intervention effects based on long-term follow-up outcomes data vs. projected distal intervention effects based on observed proximal outcomes data; 2) extend and test the application of our target efficiency approach in enhancing the benefits of translating model preventive interventions into practice; and 3) develop preliminary evidence on within-school cost consequences of the Principal Research Core interventions.
- Aim 3:** Employ these new methods in designing the RO1 supported effectiveness trials that evolve out of the Center's pilot intervention and assessment initiatives described in the Principal Research Core, and ensure that these methods are broadly disseminated for wide use.

**Principal Research Core (PRC)**. (Core Director: Leaf; Core Co-Directors: Ialongo & Bradshaw; Core Members: Alexandre, Bandeen-Roche, Boxmeyer, Brice, Feldman, Frangakis, Gittlesohn, Greenberg, Herman, Hoagwood, Lochman, Mendelson, Reinke, Salkever, Scharfstein, Slade, Stuart, Tandon, & Weist). To support the Center in achieving its mission, the PRC will:

- 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.

*See Operations Core for References*