

CENTER FOR PREVENTION AND EARLY INTERVENTION
CORE 1: OPERATIONS CORE (Dr. Ialongo, Director, Dr. Leaf, Co-Director)

1. SPECIFIC AIMS

In response to the Center PA, we propose to create a Center without walls - bringing together expertise in prevention and early intervention from within and outside JHU. One of the factors hindering more rapid development and dissemination of effective research and practice is the fact that few if any universities include the critical mass of researchers and practitioners necessary to rapidly develop, test, and disseminate school-based preventive interventions. Thus, both our Methods and Principal Research Cores integrate expertise from within and outside of JHU in addressing the critical challenges facing prevention and early intervention researchers and the mental health and substance abuse fields as a whole. The Operations Core and its Dissemination and Training Service not only link the multiple interventions led by JHU faculty, but also incorporate the Baltimore City Public Schools System (BCPSS), which is the site for our Principal Research Core initiatives, Baltimore Mental Health Systems Inc. (BMHS), and the University of Maryland Center for School Mental Health (CSMH) directed by Center Co-Investigator, Dr. Mark Weist. The link to the BMHS and the CSMH, respectively, will provide the Center with a means to disseminate the Center's intervention and assessment products to school based health clinicians throughout Baltimore and to over 10,000 practicing school mental health professionals nationwide. The Research Methods Core features the collaboration between outstanding biostatisticians here at JHU (Drs. Bandeen-Roche, Frangakis, Scharfstein, and Stuart), Dr. Jo at Stanford, and Dr. Slade at the University of Maryland. The Principal Research Core brings together leading prevention and early intervention researchers from across the nation (Dr. Dishion, University of Oregon; Drs. Domitrovich and Greenberg, Penn State University; Drs. Herman and Reinke, University of Missouri; Drs. Lochman and Boxmeyer, University of Alabama; Dr. Jaegers, University of Michigan; and Dr. Hoagwood, Columbia University) with the intervention researchers here in Baltimore (Drs. Bradshaw, Ialongo, Leaf, Mendelson, & Tandon). The Center is organized to ensure that each of the research initiatives and core center activities benefit from the interactions of our methodologists and interventionists.

The proposed Center's model for leadership and collaboration has evolved out of a 23-year partnership with the BCPSS. This long standing collaboration was initially funded in 1985 through NIMH's original prevention center mechanism and most recently (2004-present) via the ACISR mechanism—the JHU Center for Prevention and Early Intervention (JHU CPEI). In keeping with the PA, the overall goal of the Operations Core is to provide the necessary leadership and support for the success of the Center's Research Methods and Principal Research Cores and the BCPSS Practice Network. This overall goal is reflected in the Operations Core's specific aims, which are to provide:

- Aim 1:** Leadership for the Center via the **Center's Steering Committee**, led by Dr. Ialongo and made up of the Directors and Co-Directors of each of the Cores; a **Community Advisory Board**, composed of community leaders, teachers, parents, and youth; a **National Scientific Advisory Board**, composed of senior prevention and early intervention scientists, methodologists, and developmental psychopathologists outside of JHU; and the **BCPSS Practice Network**, which includes the Director of the BCPSS's Office of Research, Evaluation and Accountability and the Chief of Student Services. It will also include the Director of Baltimore Mental Health Services (BMHS) Inc, the agency designated by the state of Maryland to oversee the provision of mental health services within Baltimore City. The BCPSS Practice Network will serve as the interface between the Center and BCPSS and the BMHS. around the planning and implementation of the Center's intervention, assessment, and dissemination and training activities. The Community Advisory Board will advise the Center Steering Committee around the acceptability of the Center's intervention and assessment initiatives, whereas the National Scientific Advisory will provide feedback on the scientific value and rigor of the Center's research initiatives.
- Aim 2:** Dissemination of and training in the products (scientific papers, statistical methods and software, intervention and assessment protocols) of the Center and its collaborating scientists via annual conferences, the Internet, and an annual summer training institute.
- Aim 3:** Consultation via the Center's research ethicist on the ethical issues raised by the Center's intervention and assessment initiatives and support for the development and maintenance of a Data Safety and Monitoring Board and procedures.
- Aim 4:** Assessment services, including assistance in the recruitment, training, and supervision of assessors, retention and locating of longitudinal study participants, and the development of qualitative and as well as quantitative assessment measures and methods.
- Aim 5:** Data management services, including assistance with data entry, cleaning, and management of data from the proposed assessment and intervention work, the development of computer-assisted data collection methods, a tracking and population maintenance database, web-based documentation of the existing data, the data to be collected and the measures used to collect it, and a web-based data request system.
- Aim 6:** Administrative and logistical support for (a) the preparation of scientific papers, grant applications, and training and intervention manuals; (b) planning, scheduling, and coordinating of meetings, conferences and the summer institutes; and (c) management of budgets.

2. BACKGROUND & SIGNIFICANCE

The JHU CPEI is proposing a five-year agenda of infrastructure development, academic/community partnership building, intervention and assessment research, statistical and economic method development, and training and dissemination activities. The Center's major intervention and assessment activities are sequenced so that the Operations Core's task of tracking and coordination of the initiatives, Center faculty, and community partners involved is manageable. See Timeline of Key JHU CPEI Activities and Initiatives (below).

Activity	Team Leader & Key Center Investigators	Year 1	Year 2	Year 3	Year 4	Year 5
PRINCIPAL RESEARCH CORE INITIATIVES						
<i>Universal</i>						
1. PATHS/GBG/CCU/PBIS Integration: R34	Ialongo, Greenberg, Reinke, Herman, Bradshaw, Leaf, Embry, Gittlesohn, Slade, Bandeen-Roche					
Phase 1: Large-Scale Implementation		←→				
Phase 2: R01 Preparation & Submission				←→	←→	
2. Middle School PATHS/GBG: R34	Greenberg, Domitrovich, Jaeger, Ialongo, Scharfstein, Alexandre					
Phase 1: Developmental		←→				
Phase 2: Implementation (small scale)				←→		
Phase 3: Implementation (larger scale)					←→	
Phase 4: R01 Preparation & Submission						←→
3. Middle School Depression Prevention: R21	Tandon, Mendelson, Leaf, Weist					
Phase 1: Developmental				←→		
Phase 2: Pilot intervention trial				←→	←→	
Phase 3: Pilot trial on delivery methods					←→	←→
Phase 4: R01 Preparation & Submission						←→
<i>Indicated</i>						
4. Middle School Coping Power/PBIS/FCU Integration: R34	Bradshaw, Lochman, Boxmeyer, Reinke, Herman, Ialongo, Dishion, Hoagwood, Weist, Gittlesohn, Stuart, Alexandre					
Phase 1: Developmental		←→				
Phase 2: Implementation (1 school)			←→			
Phase 3: Implementation (3 schools)				←→	←→	
Phase 4: R01 Preparation & Submission						←→
RESEARCH METHODS CORE INITIATIVES						
Initiative 1: Study attrition	Scharfstein, Ialongo, Salkever, Slade, Stuart	←→				←→
Initiative 2: Modeling longitudinal post-treatment variables	Jo, Bandeen-Roche, Ialongo, Leaf	←→				←→
Initiative 3: Generalizability	Frangakis, Stuart, Ialongo, Leaf, Bradshaw	←→				←→
Initiative 4: Economic models	Salkever, Alexandre, Slade, Ialongo, Leaf	←→				←→
WEB-BASED INFRASTRUCTURE DEVELOPMENT						
INSPIRE Development	Domitrovich, Greenberg, Small	←→				←→
Cost-Analysis System Development	Slade	←→		←→		
DISSEMINATION AND TRAINING						
Hold Research Practice Conferences	All JHU CPEI Faculty	←→	←→	←→	←→	←→
Hold Annual Summer Institute	All JHU CPEI Faculty	←→				←→
Conduct Methods & Software Workshops	All JHU CPEI Faculty	←→				←→
Teach Graduate Level Course	All JHU CPEI Faculty	←→	←→	←→	←→	←→
Mentor Fellows & Junior Faculty	All JHU CPEI Faculty	←→				←→

2.1 OVERVIEW OF CENTER CORES

In keeping with the PA, the proposed Center is organized around 3 Cores: Operations, Research Methods, and Principal Research (see Figures 1a & 1b). We briefly summarize the key function of each Core and the work proposed over the next 5 years. The means by which the aims of the Research Methods and Principal Research will be realized are elaborated within the descriptions of each Core. In order to facilitate coordination across cores and the integration of methods development, testing of programs, training and dissemination, Drs. Ialongo, Leaf, and Bradshaw will serve as either the Director or Co-Director for each Core.

Operations Core (OC). (Core Director: Dr. Ialongo; Core Co-Director: Dr. Leaf). The Operations

Core provides scientific leadership, guidance, supportive services as needed for the Center's Research Methods and Principal Research Cores, and the BCPSS Practice Network to achieve their aims.

Research Methods Core (RMC). (Core Director: Dr. Bandeen-Roche; Core Co-Director: Dr. Ialongo). The RMC proposes to develop, apply, enhance or extend, and disseminate innovative statistical and economic methods: (1) to minimize the effects of attrition of study subjects on longitudinal study results; (2) to estimate treatment effects accounting for longitudinal post-randomization variables; (3) to assess the generalizability of randomized trial results; (4) to test for differences between distal intervention effects vs. projected distal intervention effects; (5) to enhance the benefits of translating model preventive interventions into practice by using target efficiency approaches; and (6) to develop preliminary evidence on within-school cost consequences of preventive interventions. These methods will also be employed in shaping the design of RO1 effectiveness trials that will evolve out of the Center's pilot intervention and assessment initiatives described in the Principal Research Core.

Principal Research Core (PRC). (Core Director: Dr. Leaf; Core Co-Directors: Drs. Ialongo & Bradshaw). The PRC proposes to conduct pilot and feasibility studies of efficacious and promising preventive interventions for elementary and middle school children in preparation for RO1 supported effectiveness trials of these interventions. The proximal targets of these interventions are the early antecedent risk behaviors of aggressive and disruptive behavior. The distal targets include later conduct, affective, and substance symptoms, behaviors, and disorders.

3. PRELIMINARY STUDIES

Figure 1a. The Central Role of the Steering Committee in Guiding the Center Cores

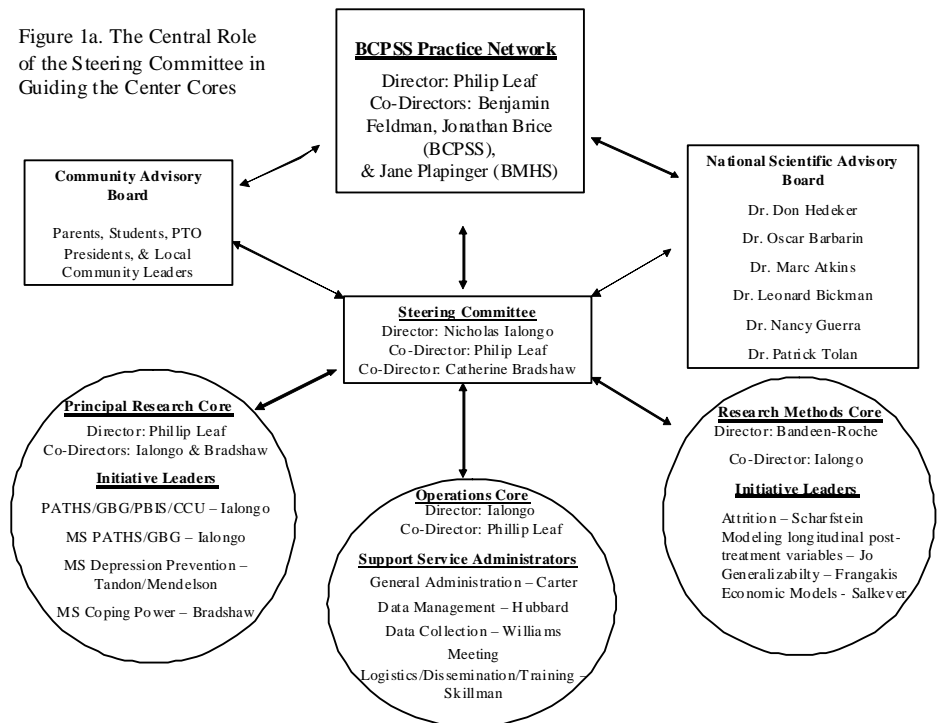
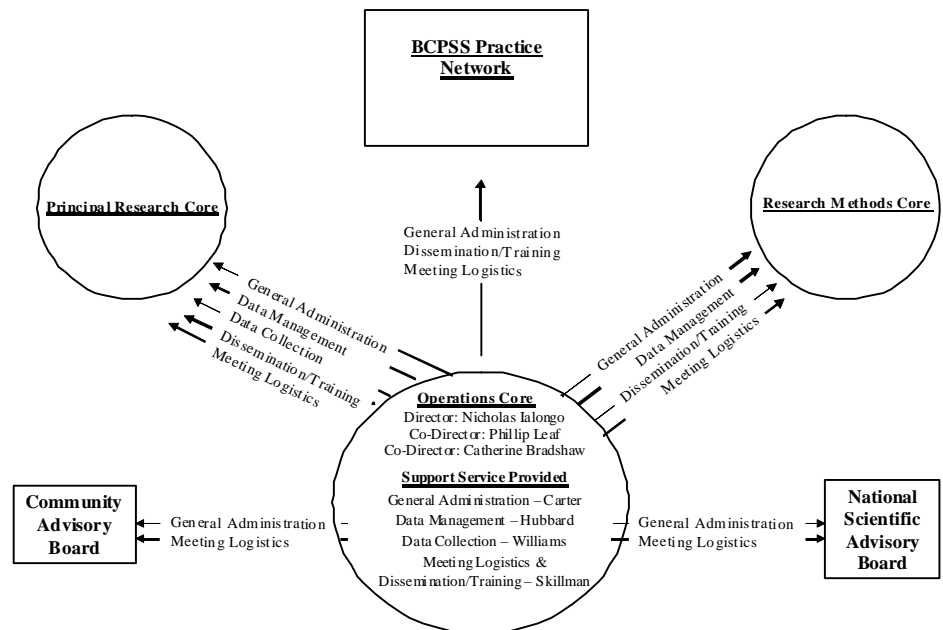


Figure 1b. The Central Role of the Operations Core in Guiding the Center and the Cores



In the OC Appendix, we provide a list of the publications and a table of grants supported (via salary support, consultation, and/or provision of data) at least in part by the current ACISR and previous generations of our JHU prevention centers. We also provide descriptions of our dissemination and training activities in the OC Appendix, including agendas from our annual research and practice conferences and workshops; descriptions of courses developed and taught by Center faculty and/or affiliated faculty with Center support; a detailed description of our web-based assessment efforts in the BCPSS, and tables of Drs. Ialongo and Leaf's minority mentees. In addition, with minor exceptions, the organizational structures, processes, and services described in the Methods section below were all developed with support from our current ACISR. Page limits preclude us from providing a more detailed description of the products of our current ACISR Operations Core.

4. METHODS

4.1 THE CENTER'S ORGANIZATION AND SCIENTIFIC LEADERSHIP

Organization and Management of the Center. Dr. Ialongo, the **Center Director**, has overall authority and leadership responsibility for specifying and guiding center policies, programs, and procedures. The **Center Co-Directors**, Drs. Philip Leaf and Catherine Bradshaw, serve as the leadership team along with Dr. Ialongo for day-to-day and week-to-week oversight and guidance of Center activities. Figure 1a depicts the Center's organizational structure and the central role of the Center Steering Committee in guiding the work of the Cores and related committees (i.e., National Scientific Advisory Board, Practice Network, and Community Advisory Board). Each of the Center's Cores has a Director and a Co-Director, who along with the Center faculty, will lead the initiatives/projects within the Cores and report to the Center Steering Committee on their progress in achieving the Center's aims. The initiative leaders within the Cores are responsible for overseeing the progress made by the research teams, including problem-solving with their teams around solutions to impediments to completing projects on time and within budget. Decision making by the Center Director and the Steering Committee will take advantage of the perspectives and judgments of the BCPSS Practice Network, which functions as a communication, dissemination, and coordination network within the BCPSS, and two different types of advisory boards. Figure 1b depicts the central role of the Operations Core in supporting the activities of the Cores and the related committees. Each committee is described in greater detail below.

The **Center's Steering Committee** will serve an integrating function, bringing together the leadership of the Center Cores (Core Directors and Co-Directors) to develop, implement and oversee a Center-wide plan for realizing the Center's aims. The Steering Committee will be led by Dr. Ialongo and made up of the Directors and Co-Directors of each of the Cores, including Drs. Leaf, Bradshaw, and Bandeen-Roche, leaders of the Practice Network (Dr. Feldman & Mr. Brice of BCPSS and Ms. Plapinger, Director, BMHS). Dr. Holly Taylor, the Center's research ethicist, who is supported by JHU Bloomberg School of Public Health's (JHBSPH) IRB, will help ensure that the Center Steering Committee carefully considers the ethical issues raised by the Center's proposed intervention and assessment activities. Given the Center is housed in the Department of Mental Health within the JHBSPH, Dr. William Eaton's (Department Chair) membership on the Steering Committee should serve to facilitate the interface between the Center, Department of Mental Health, and the JHBSPH around the department and school-wide resources (e.g., space, administrative support, computing, distance education facilities and services, meeting support and logistic services) that can be made available to the Center to ensure it realizes its aims.

The **BCPSS Practice Network** was formed through our current ACISR funding and will continue to include the Directors of the BCPSS's Office of Research, Evaluation, Assessment and Accountability (Dr. Feldman) and the Chief of Student Services (Mr. Brice), along with the Director of BMHS (Ms. Plapinger). The Practice Network is charged by BCPSS as not only serving as an interface between the CPEI and the school system, but also for monitoring the outcomes produced by all external collaborators working in Baltimore's schools. Consequently, the interventions and assessment initiatives implemented by the Center represent not only what BCPSS believes is feasible, but is consistent with the goals and mission of the BCPSS as it relates to research and evaluation, information technology, parent involvement, special education, and mental health services. The primary aims of the Practice Network are to: (1) maintain an organizational structure and process for an academic/community partnerships around the development of the necessary infrastructure for effectiveness trials of the Center's preventive and early interventions; (2) develop the infrastructure within the BCPSS for it to be an equal partner in evaluating the Center's preventive interventions; (3) set the stage for expanding the academic/community partnership between the Center and the BCPSS to include the BMHS. Drs. Feldman and Leaf and Mr. Brice and Ms. Plapinger will chair the Practice Network. The principals of the schools participating in the Center's intervention initiatives will also be included as members of the Practice Network, along with a teacher and school mental health professional from each of the participating schools. A representative of the BCPSS Office of Training Division will also serve on the Practice Network. The Center will provide funds for the BCPSS to hire a Ph.D. level school psychologist to coordinate the Center's pilot intervention activities and a Ph.D. level Research Methodologist to collaborate with Center on evaluating these initiatives. Both will serve on the Practice Network.

Advisory Boards. Our **Community Advisory Board** will provide a formal voice for parents, students, and community leaders with respect to the acceptability and relevance of the Center's intervention initiatives. The Board

will be chaired by Mr. Brice from the BCPSS and its members will include (1) the heads of the Parent-Teacher Organizations (PTO) at the participating schools; (2) parent representatives nominated by the participating schools' PTO; (3) students from the participating schools; (4) a representative from the BCPSS's Teacher Union; and (5) local community leaders (e.g., political, religious, and humanitarian). As indicated above, the Community Advisory Board will advise the Center Steering Committee and the Practice Network on the priorities of their communities and institutions and will provide feedback concerning the significance, acceptability, cultural appropriateness, and feasibility of the Center intervention and assessment initiatives. The Community Advisory Board will meet on a quarterly basis (or more often as needed) to review Center progress and initiatives, identify research questions for future initiatives, review proposed research, and provide feedback regarding the design and implement of the research in order to aid in the adoption, dissemination, and sustainability of the preventive and early interventions found to be effective. The meetings will be held in relevant community settings and other key stakeholders, parents, policy makers, and community leaders will be invited to meetings to provide advice on specific agenda items.

Our **National Scientific Advisory Board** will be composed of senior prevention and intervention scientists, methodologists, and developmental psychopathologists outside of JHU who will provide feedback on the scientific value and rigor of the Center's research initiatives. Members of the committee will offer perspectives and judgment about scientific and technical aspects of the Center's work and plans. The Board will meet on an annual basis, but will be available to meet via videoconference at least 2 additional times during the year to review center initiatives, to discuss challenges that arise, and any major changes being contemplated by Center investigators. Members of this board will review and critique the Center's progress towards its scientific aims, based on a written progress report as well as presentations at the annual meeting. The board's membership includes leaders in the fields of prevention, treatment and services research (Drs. Atkins, Barbarin, Guerra, and Tolan), biostatistics (Dr. Hedeker), and assessment (Drs. Barbarin, Bickman, Guerra, and Tolan) as well as experts on health disparities research with respect to racial and ethnic minority groups (Drs. Barbarin & Guerra). In addition, the board members will attend and participate in the Center's proposed Annual Research Conference as part of this annual review process.

4.2 THE CENTER'S DECISION MAKING PROCESS

Center Decision Making Philosophy. The Center's decision-making philosophy is oriented toward general consensus, with formal vote-taking occurring rarely and only when absolutely necessary. Differences of opinion and judgment sometimes arise among Center investigators. One source of disagreement involves understandable community sensitivity to experimental procedures (e.g., when topics of genetics research intersect with biobehavioral research on health disparities across or within minority groups). Issues of this type will be identified and addressed to the extent possible by the relevant Core Directors and initiative leaders, with the guidance from the Practice Network, the Community Advisory Board, and final decision-making by the Center Director in consultation with the Center Steering Committee and, if need be, the National Scientific Advisory Board and our NIMH program officer. In general, the Center Director will take the results of Steering Committee discussion, debate, and any formal votes into consideration, but these results are not binding. In the final analysis, the Center Director is responsible for the executive function of the Center with respect to decision-making, direction, control, and planning.

Process for Dealing with Unanticipated Events that May Have a Bearing on Whether the Center's Aims Are Realized. In the event of an unanticipated event that may jeopardize the realization of the Center aims, the Center Director will **first** convene a meeting of the Center Steering Committee, wherein the nature and scope of the problem will be discussed in detail, along with its potential implications for realizing the Center's aims. **Second**, the Center Director will initiate a process wherein members of the Steering Committee will be asked to generate possible solutions to the problem(s). **Third**, the Center Director will then review the potential solutions with the Steering Committee as a whole. The pro and cons of each solution will be discussed and a consensus will be reached regarding the most viable resolution, from both a scientific and budgetary perspective. **Fourth**, the Center Director will convene a meeting with our community partners and our Community Advisory Board to discuss the problem(s) faced by the Center and the proposed solutions. Their feedback will be elicited and the proposed solutions refined to reflect their feedback. **Fifth**, we will seek feedback and counsel from our National Scientific Advisory Board with regard to potential solutions that would maintain the scientific integrity of the Center and allow it to realize its aims. **Throughout this process**, the Center Director will keep our NIMH program officer and her supervisor informed of our deliberations and elicit their feedback as to the acceptability of the proposed solutions.

Process for Reviewing Research Proposals and Monitoring Progress of Funded Research Initiatives. The Center will continue to model its decision making process with respect to the proposed scientific initiatives in line with the NIH review process. Center investigators will develop NIH-like proposals for the work they propose to do using Center resources. These proposals will be first reviewed by the Core Directors and then brought to the full steering committee for final review with respect to significance, innovation, method, the proposed team of investigators, and whether the proposal is in keeping with the aims of the Center. Proposals will be given a priority score of 1 to 5 and ranked with respect to significance by the Steering Committee members. In the event we do not have sufficient expertise on our Steering Committee to review a proposal, outside consultants with expertise in the subject area of the proposal will be asked to review the proposal, including the members of our National Scientific

Advisory Board. Proposals involving implementation within the community will also be reviewed by the Practice Network and Community Advisory Board for significance, acceptability, cultural appropriateness, and feasibility. Once an initiative is funded, quarterly progress reports will be submitted to the Steering Committee for review.

Seed Funds for New and Innovative Research Proposals. Ten thousand dollars will be set aside in Years 4 and 5 to fund research proposals other than those described in this application from Center investigators. These proposals will be in keeping with the overall Center aims, but represent a new and innovative approach to a particular research question and or problem. The Center will model its decision making process regarding the proposed scientific initiatives after the NIH review process as described above. The Center will place a priority on awarding these seed funds to junior investigators to aid in development of K-Awards, R21s, and R01s.

4.3 THE CENTER'S LEADERSHIP MEETINGS: CREATING AN INTERFACE AMONG THE CORES AND CENTER INVESTIGATORS

Center Leadership Meetings: Frequency, Process, and Aims. In general, meetings at the team, Core, and Center level will review progress towards the study aims, timelines for completion of Center projects/initiatives, problems and resolutions, resources expended and needed, and plans and timelines for future work. Written progress reports will be required of Center investigators on a quarterly basis and decisions will be made by the Steering Committee as to whether continued funding is justified. Core Directors will also identify developments that should be disseminated to other Cores, as well as issues where consultation can be provided from the other Core members or affiliated researchers. Specifically, ***Center Steering Committee Meetings*** will be held on a bi-weekly basis in Year 1, so as to ensure the initial Center initiatives and base-building efforts with our community partners are carefully planned and implemented. In Years 2-5, it will meet on a monthly basis, given the Center's organization structure and initiatives should be well established and underway. The Center Steering Committee will be available to meet more frequently when the need arises. Drs. Ialongo (Director), Leaf (Co-Director), and Bradshaw (Co-Director), as well as the Director or Co-Directors of the Research Methods and Principal Research Cores, and key members of the Practice Network will attend the Steering Committee meetings to ensure each Core is responsive to the needs of the other Cores and that the Cores function in a highly integrated manner. A major goal of the Steering Committee will be to ensure integration of efforts across the Core components and the Center as a whole. ***Center Initiatives Planning and Progress Meetings*** will be held as needed between the Initiative teams within the Research Methods and Principal Research Cores and will include the Core Director and Co-Directors. ***Operations Core Administrative Services Meetings*** will be held weekly with the Operations Core administrative staff (described below) and Center Directors over the life of the Center. The ***Practice Network*** will continue to meet on a monthly basis at the BCPSS in Years 1-5. ***The Community Advisory Board*** will meet on a quarterly basis or more frequently depending on the timeline for fielding new initiatives that will require community sanction. The ***National Scientific Advisory Board*** (as described above) will meet on an annual basis, but will be available to meet via videoconference at least two additional times during the year to review center initiatives and discuss any challenges or proposed major changes in the direction of the Center.

Scheduling Meetings to Make the Most Efficient Use of Time of the Center's Leadership Team. There is considerable overlap in the leadership of the Center and its Cores. For example, Drs. Ialongo, Leaf, and Bradshaw serve as Director/Co-Directors of the Center and as Director or Co-Directors of the Principal Research Core. This overlap in leadership and/or membership is intentional and is designed to foster integration of effort across the Cores. At the same time, the number of meetings required by this overlap in leadership may prove overwhelming and non-productive. Consequently, we will seek to organize and schedule Center and Core leadership meetings so that when the leaders of multiple cores are brought together for a meeting, the agenda for that meeting will include the business of each of the Cores they serve as leaders of. Moreover, we will organize the temporal order of agenda topics in order to maximize productivity. In addition, we will make use of the JHU BSPH's web-based, video conferencing facilities to facilitate the participation of collaborating researchers from remote locations.

Administrative Support for Meetings. The Operations Core features a ***Meeting/Scheduling Logistics Service*** (described below), which will provide administrative support for all meetings in the form of scheduling and having a staff member available to take meeting minutes. These minutes will then be posted to the Center's web-site for review and comments by the Center investigators. The administrative staff charged with coordinating the meetings will work to ensure that Center meetings do not overlap in their scheduled times and dates.

4.4 DAY TO DAY TASKS AND RESPONSIBILITIES OF CENTER AND CORE DIRECTORS & INITIATIVE LEADERS

We briefly describe below the day-to-day tasks and responsibilities of the Center and Core Directors and Core initiative/project leaders. We first summarize some of the common tasks and responsibilities of these Center investigators and then provide brief descriptions of their unique responsibilities. In terms of their common responsibilities, the Center Director (Ialongo), Co-Directors (Leaf & Bradshaw), and the Core Directors (Ialongo, Bandeen-Roche, & Leaf) and Co-Directors (Ialongo, Leaf, & Bradshaw) will all attend the Center Steering Committee Meeting. Moreover, they, along with the Core Initiative leaders, will attend the Center and Planning and

Progress Meeting where the Core initiative leaders will be expected to report on plans and progress for their initiatives. The intervention Initiative leaders (Bradshaw, Domitrovich, Ialongo, Mendelson, & Tandon) will also serve as members of the Practice Network. All the Center investigators will contribute to the Operations Core's Dissemination and Training initiatives described below, including co-mentoring students, fellows, and faculty affiliated with the Center's collaborators. The Center methodologists (Alexandre, Bandeen-Roche, Frangakis, Jo, Salkever, Scharfstein, Slade, & Stuart) will assist Center intervention and assessment investigators in the use of the methods they develop and in designing the planned RO1 effectiveness trials.

The Center Director, **Dr. Ialongo**, will have overall responsibility for directing the CPEI and will chair the Steering Committee and Center Progress and Planning Meetings. He will serve as the Director of the Operations Core and Co-Director of the Research Methods and Principal Research Cores. He will also oversee the Center's administrative staff, which are housed in the Operations Core, and direct the Center's training and dissemination activities. Dr. Ialongo will also lead the intervention initiatives aimed at combining Promoting Alternative Thinking Strategies (PATHS; Greenberg & Kusche, 1996), the Good Behavior Game (GBG; Barrish et al., 1969), Positive Behavioral Intervention Supports (PBIS; Sugai & Horner, 2002), and the Classroom Checkup (Reinke et al., 2007) and the middle school adaptation of PATHS. **Dr. Leaf**, the Center Co-Director will serve as the Co-Director of the Operations Core and the Director of the Principal Research Core. In addition, he will co-chair the Center Steering Committee, Center Planning and Progress Meetings, and the Practice Network. **Dr. Bradshaw**, the Center Co-Director will serve as Co-Director for the Principal Research Core and lead the Coping Power adaptation in middle school as part of the Principal Research Core. **Dr. Bandeen-Roche** will serve as the Director of the Research Methods Core (RMC) and will collaborate with Dr. Jo around modeling post-treatment longitudinal variables such as compliance behavior; **Dr. Jo** will lead that RMC Initiative. **Dr. Scharfstein** will lead the RMC Initiative aimed at reducing the effects of study attrition. The RMC Initiative investigating the generalizability of randomized trial results will be lead by **Dr. Frangakis**. **Dr. Salkever** will lead the economics Initiative within the RMC.

4.5 THE OPERATIONS CORE'S LEADERSHIP, FUNCTIONS AND SERVICES: PROMOTING THE AIMS OF THE CENTER AND ITS CORE ACTIVITIES

The Operations Core integrates the scientific and infrastructure aims of this Center and is responsible for making sure that the Center Director, leadership team, and Center-affiliated investigators have access to effective administration, staffing, and deployment of resources in realizing the Center's aims. The Operations Core support functions will be organized within 5 administrative services, each headed by a Service Administrator. The Operations Core's Administrative Support Services include: (1) General Administrative (Staffing, Budget, and Purchasing), (2) Data Management, (3) Data Collection and Assessment, (4) Meeting Logistics Support and Scheduling, & (5) Dissemination and Training. The Center's Operations Core will be led by Dr. Ialongo, who will continue to serve as the overall Director of the Center. In his capacity as Center and Operations Core Director, Dr. Ialongo will ensure that Operations Core meets the needs of the Center as a whole. Dr. Ialongo has considerable research management experience, having served as the Director of the current ACISR's Operations Core for the last 4 years and Co-Director of the original Johns Hopkins Prevention Intervention Research Center (JHU PIRC) from 1992-2000. The day-to-day functioning of the Operations Core will be conducted with the assistance of Ms. Carlina Carter, the Center Administrator, Mr. Scott Hubbard, Administrator of the Data Management Service, Ms. Nadia Williams, Administrator of the Data Collection and Assessment Service, and Ms. Debbie Skillman, Administrator of the Meeting Logistical Support and Scheduling and Dissemination and Training Services. Each of these staff members are currently supported by the JHU CPEI and multiple research grants through 2012. Consequently, the Center will only cover a portion of their salary. Moreover, we expect as Center generated grants are funded, a portion of the Center administrative staff's salaries will be covered by those grants.

4.5.1 GENERAL ADMINISTRATIVE SUPPORT SERVICE

Leadership and Center Administrator Responsibilities. Ms. Carlina Carter, the Center Administrator, will be overseeing this Service as well as supervising the Administrators of the Assessment, Data Management, Meeting Logistics Support and Scheduling, and Dissemination and Training Services. She will also be responsible for managing all expenditures related to the Center's operation, recruiting and training administrative support staff; and implementing policies and procedures in accordance with Center and JHU administrative policies. She will also provide and review with the Center Director and Co-Directors on a weekly basis the status of each of the budgets for the Center's initiatives and the supportive functions of the Operations Core. In addition, Ms. Carter will be responsible for the call for, receipt, and assignment for review of applications from Center investigators for funding their proposed initiatives as described in the Research Methods and Principal Research Cores. Moreover, Ms. Carter will be responsible for organizing this information for presentation to the Center Steering Committee for decisions on each initiative and the relaying of that information to the Center investigators via the Core Directors and Center initiative/project leaders. Ms. Carter will call upon the Administrators of the Meeting Logistics Support and Scheduling, Dissemination and Training, Data Management, and Data Collection and Assessment Services when necessary to assist her in carrying out the functions of the General Administrative Service. Similarly, each of these Administrators will be called upon to assist one another from time to time in carrying out their service functions.

Service Functions: Allocation of Funds and Monitoring of Expenditures. In NIH application fashion we will expect center investigators to submit detailed budgets and budget justifications with their research proposals. Also like NIH, once a proposal is reviewed and approved, Center investigators will receive notices of award, which break down the funds within the categories specified in the proposal's budget. The budgets for each of the approved proposals will be then incorporated into the JHU SAP system (described below), wherein each funded research initiative will have its own JHU budget number. SAP allows for the minute-to-minute monitoring of expenditures via the Internet by the Center Administrator, Ms. Carter, and the Center Director and Co-Directors. Budgets will be set up so that no category can be overspent without the expressed consent of the Center Director. Ms. Carter, under the supervision of the Center Director and Co-Directors, will regularly monitor the overall Center budget as well as the budgets for the individual Center research initiatives and review the status of these budgets with the Center Director and Co-Directors on a weekly basis.

Service Functions: Personnel and Staffing Services. The General Administrative Support Service has available a library of EEO-compliant university job descriptions, as well as temporary agency contacts required for effective and prompt staffing of research projects across the range of skill-sets required for Center and research project operations. Principal investigators and faculty members affiliated with the Center will not be required to write these job descriptions or develop these contacts by themselves. Rather, this Service will provide this infrastructure support and will aid in staffing projects in response to the Center faculty members' needs.

Service Functions: Materials, Supply and Requisition Services. The Center will provide Center-affiliated faculty with supplies necessary for the performance of their functions. Ms. Carter will process all purchase requests to insure they conform with the budgets agreed upon for each Center initiative by the Center Steering Committee as described under **Allocation of Funds and Monitoring of Expenditures** above. The purchasing process has been greatly facilitated by the availability of electronic purchase orders at JHU and standing accounts with major vendors whereby materials can be purchased online via a University purchase order.

Service Functions: Protection of Human Subjects. Dr. Holly Taylor, a faculty member in the JHU Bloomberg School of Public Health and a research ethicist, will advise the Center Director on the development of a Data Safety Monitoring Committee and will lead the Committee once it is established. She will also advise Center investigators about the ethical issues raised by their research. Ms. Carter, the Center Administrator, will assist Dr. Taylor and the Center Director in establishing and supporting the Data Safety and Monitoring Board, whose composition and mission is described in the Human Subjects Section below. Ms. Williams and the Operations Core's Meeting Logistics and Scheduling Administrator, Ms. Skillman, will provide support for the Data Safety and Monitoring Board in terms of scheduling meetings and gathering and preparing the necessary materials for the Board to review. Ms. Williams, as she has done for the JHU PIRC follow-up studies, will also assist each Center investigator with the submission of the necessary protection of human subjects protocols for each of their Center initiatives. She will also serve as a liaison (when needed) with the Institutional Review Board here at the JHBSPH and counterpart IRBs at collaborating institutions.

4.5.2 DATA COLLECTION & ASSESSMENT SERVICE

Leadership, Responsibilities, and Service Functions. Ms. Nadia Williams will continue to serve as the Data Collection and Assessment Service Administrator and in this role will assist the Center's Principal Research Core investigators in the recruitment, training, and supervision of assessors, retention and locating of longitudinal study participants, and the development of assessment measures and methods. The Center will draw upon Ms. Williams' considerable experience as Assessment Coordinator for the JHU PIRC follow-up studies with the type of expansion and contraction in requirements for measurement and assessment teams associated with assessment and intervention initiatives like those proposed in the Principal Research Core. With respect to quality control, Ms. Williams and this service will rely on the structure and procedures we have developed in our follow-ups of the 1st and 2nd generation JHU PIRC field trials. During periods of assessment fieldwork, we maintain a separate quality control team (QC). The QC team is headed by an experienced team leader who also has capabilities and training to function as a line field assessor, but who is a specialist in QC editing, coding, and review of data gathered by the field assessors, whether the data collection procedure includes use of hardcopy interviews, optical scan forms, or computer-assisted procedures. The QC team leader will supervise the work of a QC team that works in the office while the assessors are in the field, and follows standardized procedures for evaluating the performance of each individual assessor and for the teams as a group. Feedback about the team's performance to QC standards will be provided during a weekly or bi-weekly meeting with the team as a group (e.g., mean number of inappropriately missing values for the team as a group), with tangible reinforcers used to shape QC improvements. In addition, the team leaders will exchange information about QC performance of the individual team members, who then receive individualized evaluations from the team leader followed by efforts to improve performance at the individual level as well as the team level, to remediate, or to terminate assessors who do not live up to QC or volume performance expectations. The use of computer-assisted measurement procedures has prompted adaptations in our organization and operation of our measurement and assessment teams and the QC teams, although each of our assessors is

trained to make use of hardcopy assessment procedures whenever possible, as a backup against equipment failure in the field.

4.5.3 DATA MANAGEMENT SUPPORT SERVICE

Leadership, Responsibilities, and Service Functions. Mr. Scott Hubbard will continue to serve as the Administrator of this Service, having served this role in the JHU PIRC and our current ACISR (CPEI), and currently providing data management support for the JHU PIRC follow-ups. Mr. Hubbard will assist Center investigators with their data management needs, including data entry, cleaning, and management of data from the proposed assessment and intervention work, the development of computer-assisted data collection methods, a tracking and population maintenance database, web-based documentation of the existing data, the data to be collected and the measures used to collect it, and a web-based data request system. Some of the research databases will include doubly-encrypted identifiers that allow linkages to identifiers such as names and addresses of participants in our tracking database. However, in many instances Mr. Hubbard has created additional databases without identifiers and without a means to link back to identifiers, encrypted or otherwise (e.g., to promote secondary investigations by investigators working under exempt research' protocols such as in the Research Methods Core). Creation and management of these three distinctively different types of databases will be the responsibility of this Service, and it will be conducted in accord with policies and principles the Center Directors and Center Initiative leaders have devised during the past 20+ years to protect confidentiality and privacy of the research participants and the integrity of the data files. We anticipate that at least several of the proposed future R01 projects will require the services of a Data Safety Monitoring Board (DSMB), and this Service is prepared for special database requirements for the DSMB and its periodic reports (e.g., adverse effects database).

4.5.4 MEETING LOGISTICAL SUPPORT AND SCHEDULING SERVICE

Leadership, Responsibilities, and Service Functions. Ms. Debbie Skillman will continue to serve as the Administrator of this Service and will be responsible for working with the Center faculty around scheduling and coordinating the various Center meetings. She will develop agendas for those meetings, take minutes and distribute those minutes, as well as maintain a log of key decisions, plans and progress. The creation of a separate administrative service to handle meetings reflects our belief that the life of a Center of this type must be organized, to some extent, around a series of meetings of Center leadership with Center-affiliated investigators, scientific advisors, and community stakeholders. Thus, one of the important administrative functions of this service is to organize and update the meeting scheduling databases that are required to perform this essential function for local meetings, as well as the accommodations required for national scientific advisory committee meetings. In the Dissemination and Training Service described below, we propose a number of Center conferences, courses and a summer institute. This service will assist the Dissemination and Training Service in providing meeting services with respect to these events, including arrangements for honorarium and travel reimbursement for speakers, meeting hall and AV arrangements, and publicity.

4.5.5 DISSEMINATION AND TRAINING SERVICE

Ms. Skillman will also continue to serve as the Administrator of the Dissemination and Training Service. More specifically, she will provide administrative and logistical support to Center investigators for (a) the preparation of scientific papers, grant applications, and training and intervention manuals and (b) planning, scheduling, and coordinating the meetings, conferences and the summer institutes described below. One aspect of the this service's support for scientific publication and grant writing involves a liaison with bibliographic services now provided by the Welch Library at Johns Hopkins through which Center investigators can use their office-based or remote web browsers to access search tools such as Medline, PsychInfo, and SCI, as well as many electronic journals and books now available on-line (e.g., see www.welch.jhu.edu). We also now maintain web-linked Procite® databases to facilitate bibliographic retrieval and citation management for proposals and new scientific articles. This service will also assist in the typing of manuscripts, grants, and intervention and assessment manuals and the production of Power Point slides and other graphics for the Center scientific presentations and institutes and courses. This Service will also facilitate the interface between Center investigators and the JHU BSPH Distance Education staff around the translation of their research findings and products (e.g., software applications, intervention and assessment manuals and protocols) into distance education course offerings.

4.6 DISSEMINATION AND TRAINING INITIATIVES/PROJECTS

4.6.1 DEVELOPMENT OF A JOINT PREVENTION AND EARLY INTERVENTION TRAINING PROGRAM WITH COLLABORATING ACADEMIC INSTITUTIONS TO EXPAND THE NUMBER OF PREVENTION & EARLY INTERVENTION SCIENTISTS

Although there are a number of centers of excellence where important research is being conducted on the implementation and sustainability of prevention and early interventions, relatively few of these research centers are affiliated with NIMH-funded prevention and early intervention research training programs. Under the leadership of

Dr. Ialongo, JHU Prevention Research Training Grant (JHU PRTP) post-doctoral training slots have been made available for fellows who are at other research centers and/or groups affiliated with the Center, including the ACISR at Arizona State University (Dr. Irwin Sandler, PI) and the Prevention Science Methods Groups at the University of South Florida (Dr. C. Hendricks Brown) and the University of California at Los Angeles (Dr. Bengt Muthen). Drs. Ialongo and Leaf participate in the 6-site, interdisciplinary training consortium for researchers in child intervention, prevention, and services mental health research R-25 Training Grant funded by NIMH with a grant to Dr. Neal Ryan of the Western Psychiatric Institute. This program annually selects approximately 20 junior faculty and postdoctoral fellows who have not obtained an RO1 award or equivalent and provides a week on-site training and a year's mentorship with one of the participating fellows and some travel funds.

As described in our Principal Research and Methods Cores, several of the research projects to be supported by the Center will be led by or heavily involve Assistant Professors, including Drs. Bradshaw, Mendelson, Reinke, Stuart, and Tandon. With support of our current ACISR, Drs. Bradshaw and Stuart submitted K-Awards, which are now funded. In addition, Dr. Jo (Research Methods Core faculty) was supported with an off-site fellowship during an earlier stage of her career and with the support of the current ACISR submitted a successful RO1 application. In addition, Drs. Ialongo and Greenberg have been honored by the Society for Prevention Research for their mentoring efforts of prevention scientists.

4.6.2 CONTINUING AND NEW CENTER INITIATIVES TO IMPROVE TRAINING IN PREVENTION SCIENCE & TO INCREASE THE INVOLVEMENT OF MINORITY FACULTY, FELLOWS, AND STUDENTS

Efforts Aimed at Increasing the Involvement of Minority Faculty, Fellows, and Students in Prevention

Research. The JHU Prevention Research Training Program (JHU PRTP, directed by Dr. Ialongo) (see OC Appendix for a complete list of previous and current trainees as well as trainees that Drs. Ialongo and Leaf have mentored or supported on their training grants), the JHU Child and Adolescent Mental Health Services Training Program (JHU CAMHSTP, directed by Dr. Leaf), and our current ACISR faculty have worked in a highly integrated fashion towards the goal of increasing the involvement of minority faculty, fellows, and students in prevention science. Dr. Sharon Lambert, now an Assistant Professor in the Department of Psychology at the George Washington University, was first a post-doctoral fellow in Dr. Leaf's CAMHSTP, then received a Diversity Supplement to one of Dr. Ialongo's RO1s and is now a first time RO1 funded investigator on a study that draws on the data collected by Dr. Ialongo as part of his continuing follow-up of the 2nd generation JHU PIRC participants. Dr. Carolyn Furr-Holden, now an Assistant Professor in the Department of Mental Health and former postdoctoral fellow of Dr. Ialongo's, also received a Diversity Supplement to one of Dr. Ialongo's RO1s, which proved to be the foundation for her first RO1. Dr. Nikeaa Linder, Assistant Professor in the JHU Department of Pediatrics, is a recipient of a Diversity Supplement to our current ACISR and is working on the development of a violence prevention program for elementary school-age African-American boys. Drs. Leaf and Ialongo also served as mentors on Dr. Harolyn Belcher's K-Award, which involved the development, implementation, and evaluation of a Head Start-based parenting intervention. Dr. Belcher is now an Associate Professor of Pediatrics in the JHU School of Medicine. Dr. Ialongo is also a mentor on Dr. Rhonda Boyd's K-Award, which seeks to develop a selective preventive intervention focusing on African-American children with a depressed mother. Dr. Boyd is a former postdoctoral mentee of Dr. Leaf's and is now an Assistant Professor of Child Psychiatry at the University of Pennsylvania School of Medicine. Also reflecting the support for minority student involvement in prevention science, Drs. Bradshaw, Ialongo and Leaf have been serving as RISE faculty mentors, which is a training program headed by Dr. Belcher and is aimed at promoting interest among African-American undergraduates and graduate students in public health. Moreover, our current ACISR has covered the costs of courses taken in the JHBSPH Departments of Mental Health and Biostatistics by ethnic minority graduate students, fellows, and faculty from Morgan State University.

Center Support for SBIR and R25 Education Grants to Develop an Online Education Course. The Center also proposes to support its faculty in writing an SBIR and/or R25 education grant to develop an online, distance education course that will be made available to other academic graduate and undergraduate institutions as well as to government agencies through the JHBSPH distance education facilities. Videotaped lectures as well other supplementary course materials will be incorporated into this online course. Students will be afforded online communications with the faculty via web-based, instant messaging at specified times, and a standing bulletin board where students can post questions and the faculty can then post their responses. The course topics will include community/organizational base building (Gittelsohn & Leaf), ethnicity and culture and their relevance to the design and theory underlying preventive interventions (Jaeger & Mendelson), theories underlying the JHU and affiliated centers' interventions (Dishion, Ialongo, Greenberg, Bradshaw, & Lochman), preventive intervention design and analysis (Ialongo & Stuart), integrating mental health services and preventive interventions (Dishion, Hoagwood, Ialongo, & Leaf), qualitative assessment methods in the development and evaluation of community interventions (Gittelsohn), cost-effectiveness analyses (Salkever & Slade), and research ethics (Taylor).

4.6.3 SUMMER TRAINING INSTITUTE

As we have done for the last 4 years within the context of our current ACISR, we will continue to support Center investigators and affiliated faculty's participation as instructors in our Department of Mental Health's Summer Institute. Besides the current Summer Institute courses being taught by our Center faculty and affiliates (see OC Appendix), which include courses on the design and analysis of group randomized designs, longitudinal analysis with latent variables, estimating the effects of mental health interventions in non-experimental settings, and Drs. Ialongo's course on prevention science, we will support Drs. Stuart and Scharfstein's (Research Methods Core) development and teaching of a Summer Institute Course on dealing with missing data, Dr. Jo's (Research Methods Core) development and teaching of a course on the estimation of the effects on preventive interventions in the presence of variation in implementation and fidelity, and Drs. Alexandre, Salkever, and Slade's (Research Methods Core) development and teaching of a course on the basics of economic analyses of preventive interventions.

4.6.4 ANNUAL RESEARCH AND PRACTICE CONFERENCE

The Center and its collaborating partners, including the University of Maryland's Center for School Mental Health, the BCPSS, and Baltimore Mental Health Systems Inc., will continue to hold an Annual Research and Practice Conference, at which Center investigators, collaborating partners, and Center affiliated fellows and students will present on the work they have accomplished over the last year. The meeting will be planned with our Practice Network and Community Advisory Board Members. It will be scheduled at a time that a significant number of the members can attend. The Practice Network and Community Advisory Board Members will be asked to offer their feedback on the significance, relevance, and acceptability of the work presented at the conference. Agendas from our previous annual conferences and practice workshops are contained in OC Appendix and include 2 jointly held conferences with the NIMH and NIDA funded Prevention Science Methodologies Group (Drs. C. Hendricks Brown and Bengt Muthen, PIs), 2 conferences on recent advances in designs and methods for drawing causal inferences in intervention and observational research, and our last conference on bringing the lessons of prevention science and genetics and neurobiology into a broader, richer shared scientific framework to organize and enhance knowledge of etiology and prevention.

Consistent with the overall aims of the Principal Research Core (PRC) and the specific PRC initiatives, a "Consensus Conference" will be held in Year 1 to review the available evidence-based preventive interventions for use with youth during the middle school years, and developmental issues to be considered when creating interventions for adolescents. The invited presenters will include Drs. Dishion, Greenberg, Lochman, Guerra, and Tolan. This conference will benefit several of the Initiatives included in the Principal Research Core, including the development of the middle school versions of PATHS and Coping Power, as well as the depression prevention program for sixth graders. Tentative topics for the Annual Research and Practice Conferences in Years 2 and 3 include establishing a consensus as to what are the evidence-based strategies for enhancing parental engagement in preventive interventions and improving intervention implementation fidelity via coaching/mentoring, respectively.

The Center's National Scientific Advisory Board will be asked to attend these Annual Research and Practice Conferences as part of their annual review of the Center's progress. We will also invite relevant experts in the fields of prevention, early intervention, biostatistics, information technology, clinical trials, and assessment to present their work. The goal of these presentations will be to inform Center investigators and collaborating partners of new methods and practices that they may want to incorporate into their ongoing initiatives. We will use Dr. Weist's Center for School Mental Health's mailing list to invite school mental health practitioners from around the country to attend.

4.6.5 RESOURCE SHARING PLAN: DISSEMINATING THE CENTER'S DATA AND ASSESSMENT AND INTERVENTION METHODS AND PROTOCOLS

For more than 2 decades, the JHU CPEI and its predecessors have endeavored to share data and research methods with researchers not affiliated with the Center. We have made existing assessment measures and intervention protocols available through our web-site (<http://www.jhsph.edu/prevention>). The proposed Center will continue to support making these protocols available via the web. Our website includes information about study designs, characteristics of data collected, codebooks, and research reports and publications using data generated by the Center. We also provide interested researchers with a mechanism for building and submitting a request for data. Center staff have been available to create data sets for researchers and students for conducting analyses and we will continue supporting access to Center-related data and assessments. Moreover, the Center will continue to support its assessment and intervention investigators in submitting SBIR's and other grants to create distance education courses for wide-scale dissemination of Center intervention and assessment protocols.

The Center will capitalize on the proposed Annual Research and Practice meetings to share our data with the faculty, fellows, and students at affiliated ACISRS and DCISRS (e.g., Arizona State University ACISR, Dr. Sandler, PI; Columbia University DCISR, Dr. Hoagwood, PI; University of Illinois at Chicago DCISR, Dr. Atkins, PI) and other research groups. Taking as a model the 2005, 2006, and 2008 annual research conferences, which were jointly held by the JHU CPEI and the NIMH and NIDA funded Prevention Science Methodology Group (Drs. Brown and Muthen,

PIs), we will make the Center data available to the methodologists at affiliated sites (e.g., University of South Florida, Dr. Brown, University of California at Los Angeles, Dr. Muthen, Arizona State University, Dr. David Mackinnon) for use in the development of new analytic methods. Likewise, the affiliated centers and research groups will make their data available for analysis by the Center's faculty, fellows, and students. The Annual Research and Practice Conferences will also be used to familiarize the affiliated faculty with each other's data.

4.7 WEB-BASED DATA COLLECTION AND IMPLEMENTATION SUPPORT INFRASTRUCTURE DEVELOPMENT

Web-Based Assessment: INSPIRE. Over the past 4 years, the JHU CPEI has supported the development of the INSPIRE program, a web-based software system that provides a structure to support the use of evidence-based interventions in schools. The system features were refined and expanded in the first phase of the JHU CPEI and this work will continue in the next phase of the Center. The current version of INSPIRE is designed to facilitate the collection and use of two types of information: data regarding student functioning and data regarding the quality of intervention implementation. INSPIRE allows users (e.g., teachers, intervention coaches, administrators) to enter and receive critical information regarding program implementation (e.g., number of PATHS lessons delivered, GBG games played, quality & fidelity of implementation) and provides a system to collect data regarding student-level risk and protective factors (e.g., social and emotional adjustment, academic needs, mental health symptoms) in a way that is less burdensome compared to traditional evaluation methods. It also has the capacity to integrate multiple sources of data and link with other web-based data collection systems (see OC Appendix for detailed description of current features). INSPIRE has a report feature that allows end users to view both types of data in isolation (e.g., individual classroom) or to a comparison group (e.g., grade level in the district) in real-time. The data warehouse archives all information that is collected so data can be viewed over time by different school personnel depending on their level of access. INSPIRE has been used by over 200 BCPSS teachers to rate student behavior and implementation of the GBG+PATHS intervention over the past two years (described in PRC Initiative 1). In the proposed Center, INSPIRE will be configured to assist in the data collection associated with all of the initiatives.

To date, INSPIRE has been primarily used as a data-collection tool, however, it has the potential to influence multiple aspects of program implementation and monitoring related to the proposed JHU CPEI Principal Research Core Initiatives. We are proposing to make two types of modifications to the system that will optimize its features and benefit the initiatives described in the PRC. The first set of modifications includes adding new functions to the assessment component of INSPIRE, which take advantage of recent advancements in web-based technology and design. Specifically, we plan to develop a "Rules Engine", which would allow the specification of a formula to create a "threshold for action" that is applied to any data in the system. A second function will enable the system to communicate with users via electronic mail. An email communication, or "tickler" will be automatically sent after the data is entered and scores are calculated. These assessment enhancements will result in a system that can be used for intervention gate-keeping between universal, selective and indicated interventions by prompting the collection of screening data and flagging eligible participants through data-defined algorithms.

The second set of modifications aims to support high quality implementation of evidence interventions, such as the GBG, PATHS, and Coping Power, which are described in the Principal Research Core. Specifically, we plan to 1) reconfigure the user interface to be more appealing to school personnel and add features that meet their needs in order to increase the frequency with which teachers use INSPIRE; 2) provide written and video training materials on-line in a way that is consistent with adult learning models; and 3) create functions that allow members of the school community to exchange ideas and provide practical and emotional support to one another. This latter set of enhancements will result in a more interactive online community to promote the high quality implementation of evidence-based interventions (e.g., PATHS, GBG, Coping Power) and engage the broader school community (e.g., principals, school mental health professionals, and coaches) in supporting teacher implementation of evidence-based interventions and monitoring program outcomes. Additional information regarding the proposed enhancements and their rationale is provided in the OC Appendix.

An Internet-Based Research Infrastructure for Collecting Data on the Within-School Costs of Students' Behavior Problems. From kindergarten through high school, students with severe behavior problems (SBPs) draw intensively on schools' resources (Cunningham et al., 2008). Students with SBPs exhibit a persistent pattern of disruptive, aggressive, and/or violent behaviors at school. Typically, these behaviors begin early in childhood and persist throughout adolescence and can result in a variety of within-school outcomes that necessitate extraordinary use of schools' resources. Outcomes associated with SBPs include special education evaluations and enrollment in special education services, visits to the principal's office, formal disciplinary proceedings for out-of-school suspensions and expulsions, and interruptions of classroom teaching. Moreover, many adolescent students with SBPs require out-of-district educational placements in more restrictive educational settings, which typically have costs exceeding \$30,000 per student per year (Cunningham et al., 2008). The total economic costs of these types of outcomes could be substantial in the many schools nationwide that have more than a few students with SBPs (Landrum et al., 2003; Bradley et al., 2008). However, information about the overall economic costs of SBPs in schools is generally unavailable, which means no standardized information is available to assess the within-school

economic benefits of research-based preventive interventions that could reduce the incidence or severity of behavior problems in schools. Consequently, our ability to demonstrate the economic value to school systems of school-based preventive interventions is limited.

Currently, assessment of the within-school costs of SBPs is extremely challenging. Absent a research infrastructure for collection of data on costs, most of the information needed for assessment is unavailable. Schools usually do not track the amount of staff time devoted to activities related to SBPs. Even in formalized school programs, such as special education programs, detailed expenditure reports usually are not maintained because such reports usually are not required for budgeting or financing purposes. Even when program expenses are recorded, these records are usually not appropriate for estimation of costs of SBPs; program expenses may be attributable to a range of services provided, only some of which were triggered specifically by SBPs. In addition, schools' records generally do not reflect indirect costs, such as opportunity costs incurred when teachers and principals take time to address SBPs.

In the next phase of the Center, we propose to develop a research infrastructure for estimation of the within-school costs of serious behavior problems among students (for further details, please see Research Methods Core—Economic Methods). The infrastructure to be developed will take the form of a structured internet-based instrument for the collection of data on direct and indirect costs in schools. We will integrate and adapt for our purposes two existing internet-based software applications, one which was originally developed to track the costs of programs in school based health centers (Caffay & Chatterji, 2007; see OC Appendix) and the other which was developed to assist provider agencies in assessing the financial impact on Medicaid programs associated with providing Medicaid Targeted Case Management services. The two applications have many features in common, as both were developed by Dr. Christine Caffray-Kreines, who has a degree in accounting as well as Ph.D. in cognitive psychology. Dr. Caffray-Kreines will be a consultant on our proposed project, along with Dr. Pinka Chatterji, a health economist, who collaborated with Dr. Caffray-Kreines on the development of the assessment tool for tracking the costs of school-based health centers. Our integrated version of the two applications will provide a customizable platform for collection of data on organizational and intervention costs in schools, and consequently will be an extremely useful platform for our subsequent RO1 evaluations of the interventions developed and pilot tested in the Principal Research Core. The two software applications have similar structures and use similar methods. Both use an Internet-based question-and-answer format to develop a database on program costs. Users enter information by proceeding through a series of survey questions presented in consecutive screens. Both applications use standard cost assessment methodologies (Gold et al., 1996). Also, both applications have sophisticated database reporting features and can be customized for new report formats. However, the second internet-based software includes additional capacity for identifying and isolating specific service costs and delineating them from total program costs. Built-in worksheets provide users with a uniform cost basis for allocating program operational costs down to the specific service level.

Relative to some other existing instruments that could be used for developing estimates of within-school costs, our proposed costing application will have several strengths. First, we will adapt the only available application that has been developed specifically for school-based programs. As a result, our application will be developed at a relatively lower cost than if the application had to be built de novo. Second, our application will be self-administered by financial and/or program staff outside of a research setting. Third, using the Internet greatly simplifies the presentation of a survey, which involves complex skip patterns and different question-pathways depending on how the user's accounting records are structured. Although some prior applications (e.g., DATCAP and SASCAP) are available in an Internet format, we will adapt applications that were developed solely for use on the Internet; consequently, they have built-in features that are not available elsewhere, such as the ability to add an automated user-feedback survey and the ability to access pull-down lists of provider types. Fourth, the Internet-based application incorporates logic and validity checks into the survey; these automatic real-time checks are not available in most existing instruments.

Our development process will begin by convening a panel of BCPSS Office of Finance and Student Services administrators and members of the Child Study, or Individual Education Plan (IEP) teams, from at least 5 of the schools participating in the Principal Research Core initiatives. The Child Study or IEP teams are charged with determining the need for special education services, development of the individual education plans for students deemed in need of special education services, and maintaining records of what was recommended and what was received in terms of services. At the initial meeting of the panel, we will present the two existing applications and seek recommendations for modifications that should be incorporated in the new application. After initial development takes place with a software developer, we will field test our prototype version of the application with Child Study team members from 10 additional Principal Research Core initiative schools and administrators from the BCPSS Offices of Finance and Student Services. In the field testing phase, cost estimates will be aggregated at the level of a school population, and averaged across the population to obtain per student costs; no individual children will be included in assessments of costs. Further modifications of the application will be made based on our experiences in the field testing phase and based on the result of the built-in user survey. We expect that the initial development

and field testing process will take 3 years. Following our initial field test of the Internet application, we will utilize the Internet-based application to develop a methodology for assessing the within-school costs and benefits of the Principal Research Core intervention initiatives (see Research Methods Core—Economic Methods). We also anticipate interest in our application from the more than 560 Maryland schools that participate in the Positive Behavioral Interventions and Support (PBIS) network (<http://pbismaryland.org/members.htm>), which Drs. Leaf and Bradshaw are members.

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 (Dr. Ialongo) and Co-Directors (Drs. 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 be 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 be 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.

6. Vertebrate Animals N/A

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8. Consortium/Contractual Arrangements

The Center represents a joint effort among a number of universities and Institutions. Thus, subcontracts are included with (1) the University of Alabama, (2) the University of Maryland, (3) Pennsylvania State University, (4) Research Foundation for Mental Health, (5) University of Missouri, (6) Baltimore City Public Schools System and (7) Stanford University.

9. Consultants/Letters of Support

As indicated in the letters of support, the Baltimore City Public Schools System and the Baltimore Mental Health Systems Inc. have agreed to implement a program of research in support of Center activities. Drs. Tom Dishion, Christine Caffray-Kreines, and Pinka Chatterjiwill serve as consultants, along with members of the National Scientific Advisory Committee.