

Section A

Introduction

A.1. Circumstances Requiring the Collection of Data

The purpose of the data collection is to evaluate the efficacy of an in-school, group-mentoring intervention designed to foster academic engagement and prevent aggressive and deviant behavior among early adolescents. The request for information is authorized by 42 U.S.C. § 285g, which includes “the conduct and support of research, training, health information dissemination and other programs with respect to ... child health, human growth and development” (see **Attachment 1**).

A.2. Purposes and Uses of the Data

The purposes of this study are to 1) increase academic engagement and prevent/reduce aggressive and deviant behavior among high-risk early adolescents; and 2) test the efficacy of group mentoring in the school setting to impact youth’s attitudes and behaviors.

Despite the increased concern with youth well-being and recent trends promoting mentoring programs, the effects of mentoring on youth aggression and school engagement have not been studied experimentally. This research involves an innovative set of interventions not previously tested in a randomized trial. This is the only way to determine the extent to which group mentoring impacts high-risk early adolescent aggression and academic engagement. Incoming sixth grade students and one parent will be recruited in two inner city Baltimore middle schools for the intervention component of the study. Randomization will occur within school. Youth will complete three in-school surveys, baseline in the fall of 6th grade and follow-up surveys in spring of 6th and 7th grades. Their parents will complete an in-home or telephone interviews once during 6th grade.

A contract is awarded to the Johns Hopkins University School of Medicine, of Baltimore, MD, Dr. Tina Cheng, PI, for this data collection (see **Attachment 8**.) Data are collected on youth outcomes, including behavior related to academic engagement and aggressive and deviant behavior; and independent variables including youth attitudes and expectations, social skills, intent/motivation, and social competence related to school and aggressive and deviant behavior, as well as parent attitudes, expectations, and involvement related to youth academic involvement and aggressive and deviant behaviors. **Attachment 2** includes a table of measures and copies of the questionnaires.

Findings will be presented at professional meetings, shared with national and state policy groups, and published in scientific journals by scientist at the Prevention Research

and our collaborators at Johns Hopkins University Medical Center. The multiple data collections allow for longitudinal analyses of correlates of aggression and school engagement. Factors, such as parent attitudes and expectations regarding fighting, will be examined in regard to incidents of fighting. School engagement is an understudied area, particularly among low SES, minority populations. These data will allow for the examination of the impact of parent and peer factors on school engagement in an urban middle school population.

Currently, two doctoral dissertations have been completed using this data. One manuscript examining the data from the pilot of the parent intervention is under review. Two manuscripts are in preparation. One examines the parent and school influences on aggression from 6th to 7th grades. The second examines the protective effect of having a non-parent adult in the lives of youth at risk for aggressive or problem behavior. Several presentations have also utilized these data. These are listed below:

Manuscript under Review:

Rath, J, Gielen, A., Haynie, D, Solomon, b, Cheng, T, Simons-Morton, B. The Factors Associated with Perceived Parental Academic Monitoring in a population of Low-Income African American Early Adolescents. Submitted to The Journal of School Health.

Manuscripts in Preparation

Jones, V, Geilen, A., Solomon, B, Haynie, D, Simons-Morton, B, Cheng, T. The influence of adults other than parents on aggression and other problem behaviors.

Botello, M, Haynie, D, Murray, K, Cheng, T, Simons-Morton, B. Parent and peer factors influencing changes in aggressive behavior among low-income, African American sixth grade students.

Presentations.

Haynie, D. Steppin' Up: A Coaching Approach to Reducing Violence and Increasing School Engagement Among Middle School Students. Invited presentation at The Sixth Annual Southern States Knowledge Conference: Youth Violence Prevention, The Center for Violence Prevention and the UTHSCSA School of Nursing, San Antonio, TX, March, 31, 2006.

Tahseen, M., Gase, L., Haynie, D. Parental and peer correlates of social norms of urban middle school students. Poster presented at the NIH Post Baccalaureate Research Festival, Bethesda MD, May 24, 2006.

Moore, S, Haynie, D. Interviews in their own words: Urban parents talk about violence. Poster presented at the NIH Post Baccalaureate Research Festival, Bethesda MD, May 24, 2006.

Rath, J., Gielen, A.C., Haynie, D.L., Solomon, B.S., Cheng, T.L., & Simons-Morton, B.G. (2005). Factors associated with perceived parental academic monitoring in a population of low-income, African-American early adolescents. Poster presentation at

the American Public Health Association Annual Meeting, December 13th , Philadelphia, PA.

A.3. Use of Information Technology To Reduce Burden

As required in 5CFR 1320.9(j), the investigators researched technological advances that might reduce participants' response burden. A web-based data collection has been developed and implemented for youth assessments. This system includes an audio option available to all youth who would prefer to listen rather than read items. Data is automatically stored on a secure server at the NICHD. A backup system using a personal server located on the hard drive of laptop computers has also been developed and implemented. Thus in the event that the web-based system is not functioning, youth are still assessed on a computer-based system. Data is stored in files on the hard drive of the laptop rendered inaccessible to youth and staff. The data files are hidden and the program by which the data files can be opened is not installed on the laptops. Parent interviews are completed using a CATI system with the exception of some semi-structured interview sections (about 25% of the interview), which require in-person administration. Assessments are at no expense to the participants and take approximately 1 hour to complete for both youth and parents.

A.4. Efforts To Identify Duplication

Ongoing monitoring of the literature on prevention of violence among youth has identified no overlapping data collections that were started since the initial OMB approval of the current study. There are some existing data on youth violence prevention programs, but these interventions do not include a mentoring component. More general mentor program evaluation data are available; however, our data collection is unique in that it employs a randomized trial design. Data collection goals and objectives have been coordinated with the school staffs and Baltimore City school district and do not represent a duplication of school activities. An NIH State of the Science Conference on Preventing Violence and other Health Risking Social Behaviors Among Adolescents was held on October 13-15, 2004. In the final statement, panelist indicated that effective and

promising intervention efforts have been found. However, there was also call for research that takes into account different trajectories of behavior and attention to developmental milestones, such as transitions between schools. The mentoring component of this research allows for individualization of the intervention program, thus addressing differences in behavioral trajectories, and individual risk and protective factors. The program targets 6th graders, focusing on the critical transition from elementary to middle school.

A.5. Small Business

No small businesses are involved in this study.

A.6. Consequences of Not Collecting the Information

Parents are interviewed once during youth's 6th grade year, and youth are interviewed three times over a period of about 2 years. Youth baseline interviews are conducted in the fall of 6th grade to establish the basis for comparing the effects of the intervention in the two conditions. Follow-up assessments of youth will be conducted in the spring of the 6th and 7th grade to assess proximal and longer term intervention effects.

This is the minimum frequency of data collection consistent with the objectives and study design. Accurate and current information at these time points are necessary because adolescent aggression is known to increase over the course of early adolescence without intervention.

A.7. Special Circumstances Justifying Inconsistencies with Guidelines in 5 CFR 1320.6

This research study fully complies with 5 CFR 1320.6.

A.8. Consultation Outside the Agency

A. Response to Notice in the Federal Register.

The 60-day notice soliciting public comments about this study was published in the Federal Register on April 30, 2003, pages 23151-23152 (see **Attachment 5**). No public

comments were received. The 30-day notice was submitted for publication in the Federal Register in conjunction with the submission of this paperwork reduction act submission (see **Attachment 5**).

B. Review by Outside Experts and Agency Representatives

An advisory board comprised of both academics and community representatives meets monthly to review progress of the study and give recommendations on issues that arise. Through these on-going consultations, no unsolvable problems have been identified. An additional outside review took place as of the Prevention Research Branch's research portfolio during the Site Visit of the Division of Epidemiology, Statistics, and Prevention Research, on November 7-9, 2004. The study was reviewed favorably, with comments on the incorporation of theoretical concepts and attention to program quality and implementation. The names and contact information for both of these groups is found below. The study PI and Project Director meet monthly with school representatives to review study progress and procedures. Finally, annually focus groups are conducted with teachers and students regarding the intervention and measurement.

Steppin Up Study Advisory Board

M. Chris Gibbons, Associate Director
Johns Hopkins Urban Health Institute
111 Market Place, Suite 850, Baltimore, MD 21202-4036

Deborah Knight-Kerr, Director
HR Community & Education Projects
600 N. Wolfe Street Phipps Suite 428, Baltimore, MD 21202-4036
410-955-1488; dkkerr@jhmi.edu
Dwight Lassiter, HR Coordinator, Hopkins-Dunbar Partnership
600 N. Wolfe Street Phipps, Rm. 473B, Baltimore, MD 21202-4036
410-502-5963; dlassit@jhmi.edu

Phil Leaf, PhD, Director
Center for the Prevention of Youth Violence
624 N. Broadway, Baltimore, MD 21205;
410-955-3962; pleaf@jhsph.edu

Site Visit Reviewers

Robert Foss, PhD, Research Scientist
Highway Safety Research Center
University of North Carolina
730 Airport Road, CB 3430, Chapel Hill NC 27599-3430
9190962-8702; rob_foss@unc.edu

Andrea Gielen, ScD, Professor
Johns Hopkins University, Bloomberg School of Public Health
624 N. Broadway, Baltimore, MD, 21205
410-955-2397; agielen@jhsph.edu

Suzanne Bennett Johnson, PhD, Professor and Chair

Department of Medical Humanities and Social Sciences
Florida State University College of Medicine
Call Street at Stadium B 247, Tallahassee, FL 32306
850-644-8462; suzanne.johnson@med.fsu.edu

John B. Lowe, MPH, DrPH, Professor and Head
Community and Behavioral Health, College of Public Health, University of Iowa
200 Hawkins Drive, E225A, GH, Iowa City, IA, 52242-1008
319-384-5383; john-lowe@uiowa.edu

Deborah J. Toobert, PhD,
Oregon Research Institute
1715 Franklin Blvd., Eugene OR 97403
541-484-2123; Deborah@ori.org

School Contact Personnel

Dunbar Middle School
Betty Donaldson, Principal
Mary Carter-Cross, School Coordinator
Ruth Brogden, 6th grade administrator (2003-2005)
Sharlette Jones-Carnegie, 6th grade administrator (2005-2006)

500 N. Caroline Street, Baltimore, MD 21205
410-396-9296

Highlandtown Middle School
Veronica Dixon, Principal
Shenita Baldwin, School Coordinator
Fay McLean, 6th grade administrator then acting principal

101 S. Ellwood Street, Baltimore, MD 21224
410-396-9133

Chinquapin Middle School
Deborah King, Principal
Jessica Brown, School Coordinator
S. Wright, 6th grade administrator

900 Woodbourne Avenue; Baltimore, MD 21212
410-396-6424

A.9. Payments or Gifts to Respondents

Parent respondents receive \$20 cash each time they complete an interview. Our experience on the study thus far indicates that parents are generally interested in this topic

and willing to respond to questions of this nature. Hence, we believe this small incentive is sufficient to induce many parents to participate; however, it is not sufficient to force anyone to participate against her or his will. Youth will not receive payment or incentives because they will complete surveys during school during times that will not interfere with their core course work or result in additional classwork or homework.

A.10. Assurance of Confidentiality

Study participants are assured that the data collected will be safeguarded closely and that actions will be taken to protect confidentiality. Access to the youth data files is limited research staff having specific computer software to read the data and access to the secure NICHD server. Parent data will be coded and stored without personal identifiers in password protected computer files and a locked filing cabinet maintained by the contractor(s). The Principal Investigator of the contract is responsible for maintaining in a separate, locked cabinet, a list linking each coded source of data with personal identifiers. No personal identifiers are associated with individual answers on reports or publications. Only aggregate results are and will be reported. The contractors have been involved in other federally funded research projects and have developed standard procedures for assuring the quality and confidentiality of data.

Privacy Act

The name of the Privacy Act System is Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HSS/NIH/NICHD (system number 09-25-0153), which was published in the Federal Register on Friday, January 20, 1995 (see **Attachment 6**).

Institutional Review Board

The NICHD Institutional Review Board (IRB), which is DHHS-authorized (FWA 000008), approved our annual renewal application on April 25, 2006 (see **Attachment 6**). The application will continue to be reviewed annually. The study is also reviewed by the Johns Hopkins School of Medicine IRB (FWA 00005752) and was approved for renewal on April 3, 2006 (see **Attachment 6**).

Consent Procedures

Youth and parent study participants are informed about the goals and requirements of the study by a trained research assistant and provide written consent and assent on the forms included in **Attachment 4**. The study participants have an opportunity to ask questions at that time and are provided with a telephone number they can call if they have questions in the future. Respondents can refuse to participate or withdraw from the study at any time. A certificate of confidentiality was obtained to help protect the study participants' answers from the risk of disclosure; it was issued September 12, 2003 and expires August, 30, 2008.

Also found in **Attachment 4** are the materials used with the schools to inform and recruit participants to the study.

A.11. Questions of a Sensitive Nature

We collect potentially sensitive data, including aggressive and violent behavior, and substance use. In addition we collect school record information about participants' grades and disciplinary history from the school administrators at participating schools. This information is needed to evaluate the study outcomes. We obtain consent from parent and youth to collect this information. Randomized trials such as this one require that data be collected on the same individuals over time; hence, it is not possible to collect information anonymously.

Upon recruitment, study participants are explained the purposes of the study and the nature of the questions that will be asked. Parental consent and early-adolescent assent is

obtained according to the procedures approved by the NICHD Institutional Review Board. Maintaining the confidentiality of data collected is important, both to protect the right of subjects' privacy and to assure honest reporting. Substantial evidence suggests that teens tend to report honestly about their behavior when confidentiality is assured (Campanelli, Dielman, & Shope, 1987; Hanson, Malotte, & Fielding, 1985; See **Attachment 7** for References).

A.12 Estimates of Response Burden

The estimated annual response burden for collecting the information in the entire study is listed in Tables A.12-1 and A.12-2. A total of 877 respondents, 577 youth and 300 parents, are expected to participate. Sixth grade students and their parents will be recruited in fall of 2006; 7th grade students have been recruited already. Sixth grade students will be assessed twice, parents and 7th grade student will be assessed once. Given our experience with these assessments, we estimate that each data collection will take an average of 1 hour to complete and the hourly wage cost to the respondents is estimated to be \$15 per hour. The overall annual total time burden is 1,177 hours, and the annual cost burden estimate is \$17,655.

A.12.1. Number of Respondents, Frequency of Response, and Annual Hour Burden

A.12.1 Estimate Of Burden Hours

Respondent Type	Number of Respondents	Frequency of Response	Average Time Per Response	Annual Burden Hours
1. 6th graders	300	2	1:00	600
2. 7th graders	277	1	1:00	277
3. Parents	300	1	1:00	300
Totals	877			1,177

A.12.2. Hour Burden Estimates by Each Form and Aggregate Hour Burdens

A.12.3. Estimates of Annualized Cost to Respondents for the Hour Burdens

Respondent Type	Number of Respondents	Frequency of Response	Hourly Wage Rate	Respondent Cost
1. 6th graders	300	2	\$15	\$9,000
2. 7th graders	277	1	\$15	\$4,155
3. Parents	300	1	\$15	\$4,500
			Total	\$17,655

A.13. Estimate of Total Capital and Startup Costs/Operation and Maintenance Costs to Respondents or Record Keepers

There are no capital costs, operating costs, and/or maintenance costs to report.

A.14. Estimates of Costs to the Federal Government

a.) Contract Costs

NICHHD has contracted with the Johns Hopkins University School of Medicine (JHU) in Baltimore, Maryland, to conduct the study. The total funded cost over a 5-year period is \$2,842,586 for an average annual expense of \$568,517. Total estimated contract costs are \$3,050,782 and annual average contract costs are \$610,156.40. Estimated average annual contract expenses by category are included in Table A.14-1.

Table A.14-1 Average Annual Contract Costs by Category

Category	JHU
Direct Labor	\$280,856.60
Indirect Costs	\$213,431.20
Travel	\$10,680
Subcontracts	\$80,976
Other Direct Costs	\$23,852.60
General and Administration	\$360
Total Costs	\$610,156.40
Fixed Fee	\$ 41,490.64(6.8 %)

Category	JHU
Total	\$651,647

b.) Annual Costs to NICHD

Staffing for this study includes the principal investigator, 25% effort; one post-doctoral fellow, 50% effort; two other staff at 20% each; one pre-doctoral fellow, 50%; and one prebaccalaureate fellow, 50%. Total staff effort is 2.3 FTE. The estimated annual cost of the 2.3 federal employees working on the project, including salary and fringe benefits, is \$179,400. Total travel and related study expenses for these staff is estimated at \$12,500 per year. The total annual federal employee expenses, including salaries and travel, is \$191,900.

c.) Total annual costs to the Government

The estimated total annual costs to the government, adding the costs from A.14 (a) and A.14 (b) are \$651,647 plus \$191,900 for a total of \$843,547.

A.15. Changes in Burden

The current annual OMB inventory is 2887 hours. This request is for 1177 annual burden hours, a reduction of 1710 hours. The first application included a one time assessment of 7th and 8th grade students in the first year of the study, and included six assessments of students, beginning at the start of 6th and four assessments of parents. The current application does not include the one time assessment of 7th and 8th grader students, as that component of the measurement has been completed. The number of assessments for each student has been reduced to three, and number of assessments for parents has been reduced to one due to changes at the school level and tracking issues. Thus fewer annual burden hours are needed to complete the study.

A.16. Plans for Publication, Analysis, and Schedule

Data will be analyzed to determine the predictors of early adolescent aggression and school engagement, effect of adult expectations regarding aggression and academic engagement, and effectiveness of the intervention, comparing treatment and control conditions. Research questions include 1) Which factors are associated with academic engagement and aggressive behavior?; 2) Does exposure to the intervention improve youths' intent/motivation and social competence?; 3) Do improved intent/motivation and social competence increase academic engagement and decrease aggressive and deviant behavior?; and 4) Does exposure to the intervention alter parenting attitudes, expectations, and involvement?

Project Timeline

Activity	Overall Time Schedule (in months from 2006 OMB submission)
Conduct baseline survey (within a month of recruitment)	3-6
Conduct survey in Spring of 6 th grade	6-10
Conduct survey of 7 th grade	6-10
Conduct survey of parents	2-10
Obtain information from school records	6-13
Analyze data and prepare reports and papers	11-36

A.17. Approval to Not Display Expiration Date

The OMB expiration date will be displayed appropriately

A.18 Exceptions to Item 19 of OMB Form 83-I

No exceptions requested.