Attachment 6

Federal Register Notice of the Privacy Act System (in separate file, A6 privacy act.pdf)

IRB Approval from NICHD (Federalwide Assurance Number 0000008)
Signed Form NIH-1195-1

IRB Approval from JHU (Federalwide Assurance Number 00005752)

Renewal 3/28/06

CLINICAL RESEARCH PROTOCOL **CONTINUING** REVIEW APPLICATION	PROTOCOL NO. 03-CH-N261	PRINCIPAL INVESTIGATOR (Name, Institute/Branch, Address, Telephone): Bruce Simons-Morton NICHD/PRB, 6100 Exec. Blvd., 301-496-5674

PROTOCOL TITLE: Steppin' Up: Positive Youth Development Program

ACTION REQUESTED:
- ■ Renew -New subject accrual to continue
- □ Renew -Enrolled subject follow-up only
- □ Terminate -Protocol discontinued (describe briefly in the attached narrative.)

HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW?
- ■ No
- □ Yes (Describe briefly in the attached narrative)

SUMMARY OF PROTOCOL SUBJECTS:

NIH	All Other Sites	
	1120	Accrual ceiling set by IRB
	328	New subjects accrued since last review
	710	Total subjects accrued since protocol began (If accrual has been less than expected, discuss in the attached narrative.)

REQUESTED ACCRUAL EXCLUSION (Check all that apply):
- ■ None
- □ Male
- □ Female
- □ Children
- □ American Indian/ Alaskan Native
- □ Other: _____
- □ Asian
- □ Black or African American
- □ White
- □ Hispanic or Latino
- □ Native Hawaiian or Pacific Islander

HAVE THERE BEEN ANY CHANGES IN THE SUBJECT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?
- ■ No
- □ Yes (Explain changes in the attached narrative)

HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?
- ■ No
- □ Yes (Explain changes in the attached narrative)

HAVE ANY UNEXPECTED COMPLICATIONS OR SIDE EFFECTS BEEN NOTED SINCE THE LAST REVIEW?
- ■ No
- □ Yes (Identify and explain in the attached narrative)

HAVE ANY SUBJECTS WITHDRAWN FROM THIS STUDY SINCE THE LAST IRB APPROVAL?
- ■ No
- □ Yes (Discuss in the attached narrative)

HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH, THAT MIGHT AFFECT THE IRB'S EVALUATION OF THE RISK/BENEFIT ANALYSIS OF HUMAN SUBJECTS INVOLVED IN THIS PROTOCOL?
- ■ No
- □ Yes (Discuss in the attached narrative)

CHANGE IN PRINCIPAL INVESTIGATOR: ■ No □ Yes
Delete: _____
Add: _____

HAVE ANY ASSOCIATE INVESTIGATORS BEEN ADDED OR DELETED SINCE THE LAST REVIEW?
- □ No
- ■ Yes (Identify all changes in the attached narrative.)

CHANGE IN MEDICAL ADVISORY INVESTIGATOR: ■ No ☒ Yes
Delete: _____
Add: _____

CHANGE IN RESEARCH CONTACT: ■ No □ Yes
Delete: _____
Add: _____

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET, etc.):
- ■ None
- □ Medically indicated
- □ Research indicated (Complete NIH-88-23a, and attach to this application. Send a copy of entire protocol and NIH-88-23a to Chair, Radiation Safety for concurrent review).
  - □ Research usage HAS NOT changed since originally approved by the IRB and RSC
  - □ Research usage HAS changed since originally approved by the IRB and RSC (explain changes in the attached narrative)

INVESTIGATIONAL NEW DRUG/DEVICE: ■ None □ IND □ IDE
FDA No. _____.
Name: _____.
Sponsor: _____.

LIST ALL COMMERCIAL OR OTHER ENTITIES PROVIDING INVESTIGATIONAL DRUG/DEVICE:
_____
_____

HAVE ANY NON-NIH INVESTIGATORS OR SITES BEEN ADDED SINCE THE LAST REVIEW?
- ■ No
- □ Yes (Identify the persons or sites and describe the collaboration in the attached narrative)

HAVE ANY INVESTIGATORS DEVELOPED EQUITY, CONSULTATIVE, OR OTHER FINANCIAL RELATIONSHIP WITH A NON-NIH SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST?
- ■ No
- □ Yes (Append a statement of disclosure)

The Principal Investigator must attach to this application: (1) a copy of the current consent/assent documents and (2) a memorandum to the IRB Chair that addresses any "yes" responses to the above questions, and that includes a concise statement regarding protocol progress to date and reason(s) for continuing the study.

SIGNATURE	Principal Investigator	D. Haynie for B. Simons-Morton (Print/Type Name)	Date 3-17-06	Send to Accountable Investigator
RECOMMENDATION	Accountable Investigator	R. Iannotti (Acting Chief) (Print/Type Name)	Date 3-17-06	Send to Branch Chief, or CC Dept. Head of PI
	Branch Chief or CC Dept. Head of P.I.	R. Iannotti (Acting Chief) (Print/Type Name)	Date 3-17-06	Send to Clinical Director
APPROVALS	Clinical Director	S. KALER (Print/Type Name)	Date 3/21/06	Send to Chair, Institutional Review Board
	Chair, For Institutional Review Board	Ann McNemar (Print/Type Name)	Date 5/11/06 Protocol & Consent Approved Effective	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	Protocol Specialist	Date 5/24/06		

JOHNS HOPKINS
MEDICINE
SCHOOL OF MEDICINE
Website: http://irb.jhmi.edu

Office of Human Subjects Research
Institutional Review Boards

1620 McElderry Street / Reed Hall, Suite B-130
Baltimore, MD 21205-1911
(410) 955-3008
(410) 955-4367 Fax
E-mail: jhmirb@jhmi.edu

JHM-IRB 1

CONTINUING REVIEW APPROVAL NOTICE EXPEDITED REVIEW

TO : Tina Cheng, MD/MPH
Chief, General Pediatrics and Adolescent Medicine
Park 392
The Johns Hopkins Hospital

FROM: Howard Lederman, M.D., Ph.D.
Chairman - JHM-IRB 1

DATE: **04/03/2006**

RE : **Application Number: 03-04-07-08, entitled, Steppin' Up: Positive Youth Development Program (with Barry Solomon, Philip Leaf, Deborah Knight-Kerr, M. Chris Gibbons, Vanya Jones)**
Pediatric Risk Category 45 CFR 46.404 and/or 21 CFR 50.51
Form A Version 9, dated 04/19/2006.

I am pleased to inform you that the **JHM-IRB 1** approved the continuing review application for the above-referenced research on **03/28/2006.** Approval of the research is for the period of **03/28/2006 to 03/27/2007.** As principal investigator of the research, you are responsible for fulfilling the following requirements of approval:

1) The co-investigators listed on the application should be kept informed of the status of the research.

2) Changes to the research must be submitted on a "**Changes in Research Application**" to the JHM IRB for review and approval prior to the activation of the changes, with the following exception: changes made to eliminate apparent immediate hazards to the research participant may be instituted immediately and the JHM IRB should be informed of such changes promptly. The application number assigned to the research should be cited in all correspondence.

3) Reports of unanticipated problems involving risks to participants or other must be submitted to the JHM IRB in accord with the JHM IRB Guidance: Report of Unanticipated Problems Involving Risks to Participants or others, using the Problem/Event Report Form (on the JHM IRB Website).

4) Only consent forms with a valid approval stamp may be presented to participants. All consent forms signed by participants enrolled in the research should be retained on file. The Office of Human Subjects Research conducts periodic compliance monitoring of approved research and consent documentation review is part of such monitoring.

5) Federal regulations require review of approved research not less than once per year. **Therefore, a continuing review application must be submitted to the JHM IRB office six weeks prior to the above expiration date of 03/27/2007. This will allow sufficient time for review of the application to be completed prior to the expiration date.** Failure to submit a continuing review application prior to the expiration date will result in termination of the research, at which point new participants may not be enrolled and currently enrolled participants must discontinue participation in the study.

HL:kjk

Enclosures