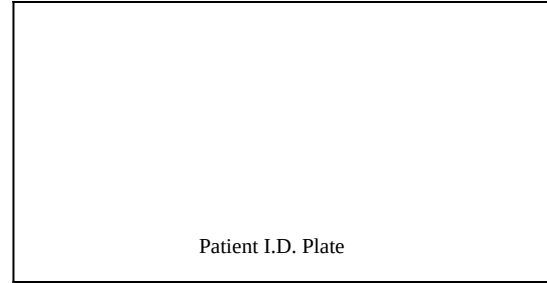


Attachment 4

Informed Consent and Assent forms
Accompanying Letter from Schools
Recruitment Brochures
Study Information Sheet

Sites of Research Protocol:
Baltimore City Public Middle Schools



RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

Protocol Title: *Steppin' Up*: Positive Youth Development Program

Application No.: 03-04-07-08

Sponsor: The National Institute of Child Health and Human Development
Rockville, MD

Principal Investigator: Tina Cheng, MD, MPH
Director, Division of General Pediatrics and Adolescent Medicine
The Johns Hopkins University School of Medicine

Date/Revision: July 6, 2005

1) What you should know about this study :

- You are being asked to join a research study.
- This consent form explains the research study and your part in the research study.
- Please read it carefully and take as much time as you need.
- Ask questions about anything you do not understand now, or when you think of them later.
- You are a volunteer. If you do join the study and change your mind later, you may quit at any time without fear of penalty or loss of benefits.
- While you are in this study, the study team will tell you any new information that could affect whether you want to stay in the study.
- The word "you" in this consent form will refer to both you and your child.

2) Why is this research being done?

This research is being done to learn more about how to encourage children to stay involved in school, get along with family and friends, and stay healthy and safe. The research will test the *Steppin' Up Program*. The program is sponsored by the National Institute of Child Health and Human Development (NICHD) within the legislative authority of Section 448 of the

Public Health Service Act 42USC(285) in association with The Johns Hopkins University School of Medicine and your child's middle school. About 1400 students and their parents/guardians are expected to participate. All 6th grade students in your child's middle school, and their parents/guardians, may join this study. Project staff will be working with teachers to help your child transition to middle school.

3) What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

1. After receiving signed consent forms, your child will be randomly (like the flip of a coin) put into one of two groups. Both groups will receive information about the importance of school involvement and staying healthy and safe. Your child may also participate in a 10-12 week session, either in the fall or spring of his/her 6th grade year. Session activities will be held during the school day. Voluntary field trips and other special activities will also be held throughout the school year. The activities will be directed by a session leader from the Johns Hopkins staff who is trained in the program goals and objectives. Trained adult coaches will participate in group activities. Coaches may also contact students participating in weekly sessions by phone or through visits outside school. Session activities may involve photographing and/or videotaping to provide creative opportunities for students to express themselves. Photographs and videotapes will be used for class activities and presentations. They may also be used for showing the program on the school television system and in school newsletters related to the Steppin' Up Program.
2. You will periodically receive program information by phone, mail, or through the school during your child's 6th grade year. You may be invited to participate in an interview at your home or group meetings at a conveniently located site to discuss the program and issues related to parenting a 6th grader. You may be contacted to participate in a program that involves home visits and telephone coaching sessions designed to increase parent involvement.
3. Your child will complete a survey (about one hour in class) twice each year from grades 6–8 about the program and attitudes and behaviors related to school involvement and staying healthy and safe. Study staff will contact your child's teachers and review your child's past and current school records, including attendance, grades, and disciplinary information.
4. You will be asked to complete up to four in-person or telephone interviews (about 20 minutes each) about similar information twice during your child's 6th grade year and once during his/her 7th and 8th grade years.

4) What are the risks or discomforts of the study?

The risk of this study is a loss of your confidentiality. It is possible that someone not involved in this research study may see information about you. However, the research group will not tell you or other people the information your child tells us unless the law requires us to tell someone (like if a child says they have been abused by an adult, if a child plans to hurt someone else, or if a sexually transmitted disease has been reported). In some instances, research staff may notify school administrators if the staff member believes a child is in danger, or poses a significant threat to others. Also, some interview questions may be

considered sensitive in nature. Neither you nor your child has to answer any questions that might make you uncomfortable.

5) Are there benefits to being in the study?

Your family will receive information about staying involved in school, getting along with family and friends, and staying healthy and safe that you might find helpful. Materials about community resources will also be provided. Information we gather from your family may benefit programs and services for children and families.

6) What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your status at school will not be affected. If you do join, and later change your mind, you may quit at any time.

7) Will it cost you anything to be in this study?

The *Steppin' Up Program* is free of charge. Any costs you may have to pay if you are injured in this study are explained in Section 13 (c) below.

8) Will you be paid if you join this study?

You will receive \$20 by mail for each parent/guardian phone survey you complete.

Parents/guardians who participate in the interviews and meet in groups will receive an additional cash or gift incentive worth \$25. Snacks or pizza will be brought to some of the home visit sessions.

9) Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

10) Why might we take you out of the study early?

You may be taken out of the study if:

1. You fail to follow instructions.
2. The study is cancelled.

There may be other reasons that we don't know at this time to take you out of the study.

11) What safeguards will be used to protect your privacy?

Johns Hopkins has rules to protect information about you. Federal and state laws also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

Generally, only people on the research team will know that you are in the research study and will see your information. However, there are a few exceptions that are listed later in this section of the consent form. Unless you give permission or the board that reviews research studies approves it, no one else will be able to see or use your information.

Some of the information about you will be collected in public, such as through the focus groups and other activities with your classmates. Other information will be collected in private, such as through interviews with your teachers, questionnaires you fill out, or through a review of your school records. The only people who will see the information collected privately about you are members of the research team. There are a few limited exceptions that are discussed later in this section of the consent form. Otherwise, no one else will be able to see or use the privately collected information about you, or provided by you during the research, unless you give your written permission. When the study is over and the results are public, no information linked to you will be included unless you give your written permission.

a. What information about you will be collected in this study?

The study team may collect information about you that relates to your attitudes about school, friends, and your family. They will collect information about how you think about your health and safety. They also will see information about your school record, including your grades, attendance, and disciplinary record.

Other information about you that the study team may collect includes:

- your name
- your address
- your telephone number
- your date of birth
- your Social Security number
- other details about you.

b. Who at Johns Hopkins might see or give out information about you, and why?

In limited situations, the study team may have to share your privately collected information because the government or a court requires them to. Sometimes other people at Johns Hopkins may see or give out your information. These include people who review the research studies, their staff, lawyers, or other Johns Hopkins staff.

c. Who else outside of Johns Hopkins might see the privately collected information?

In limited situations, some government groups outside of Johns Hopkins may need to see the privately collected information. Even these groups do not usually ask to see information in a form that would identify you. These groups include parts of the federal government that have a legal duty to protect research participants, such as:

- the Office of Human Research Protections

Other people and organizations involved with this study may see your health information. These include:

- The sponsor of this study and people that the sponsor may contract with for this study. The name of the sponsor is The National Institute of Child Health and Human Development.

- People who may provide administrative or similar support activities to the research team (copying, data-input, etc.).

d. Why will this data be used and given out?

Your privately collected data will be used and given out as described in this part of the consent form only to complete this research study and to analyze the results.

e. What if you decide not to give your permission for this use of this privately collected information?

We cannot do this research study without your permission to use and give out this privately collected information for the purpose of this study. You do not have to give us this permission. If you do not, then you may not join this study.

f. How long does this privacy authorization last?

We will use and disclose your information only for the purposes stated in the study. The use of your information has no time limit. You can cancel your permission to use and disclose your information at any time by calling the Johns Hopkins Medicine IRB at 410-955-3008 or by sending a letter to:

Office of Human Subjects Research
1620 McElderry Street
Reed Hall, Suite B130
Baltimore, MD 21205-1911

Your cancellation would not affect information already collected in this study

g. Is the privately collected information protected after it has been given to others?

Johns Hopkins has agreements with organizations to protect the use of this information. However, if this information is given to someone not covered by these policies and laws, there is a remote chance that this information would no longer be protected.

12) What if there is a Certificate of Confidentiality for this study?

The National Institute of Child Health and Human Development issued a Certificate of Confidentiality for this study. This document protects the study data. It also protects your privacy from federal, state, or local court or public agency action. The research team will not give out study information about you to a court or public agency without your consent. However, there are some exceptions to this protection. Maryland law requires the research team to tell the local or state authorities:

- if they suspect abuse or neglect of a child or dependent adult;
- if certain diseases are present; and
- if the team learns that you plan to harm someone. In this case, the team also may warn the person who is at risk.

The team may also report suspected spouse abuse to the police.

13) What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008.

b. What do you do if you have questions about the study?

Call the principal investigator, Dr. Tina Cheng, MD, MPH, at (410) 614-3862.

c. What should you do if you are injured or ill as a result of being in this study?

Call Dr. Tina Cheng, MD, MPH, at pager (410) 389-0242, if you have an urgent medical problem related to taking part in this study. **After the tone, enter the phone number where you can be called, press the # key, and hang up.**

Call the person in charge of this study, Dr. Tina Cheng, MD, MPH, at (410) 614-3862, if you think you are injured or ill because of this study.

Medical care at Johns Hopkins is open to you as it is to all sick or injured people. Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. The costs for any treatment or hospital care would be charged to you or your insurance company.

d. What are the Organizations that are part of Johns Hopkins?

Johns Hopkins includes the following:

- The Johns Hopkins University
- The Johns Hopkins Hospital
- Johns Hopkins Bayview Medical Center
- Howard County General Hospital
- Johns Hopkins Community Physicians.

14. Assent Statement

This research study has been explained to my child in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

15) What does your signature on this consent form mean?

Your signature on this form means that:

- you understand the information given to you in this form
- you accept the provisions in the form
- you agree to join the study

You will not give up any legal rights by signing this consent form.

WE WILL SEND YOU A COPY OF THIS CONSENT FORM.

NOT VALID WITHOUT THE IRB STAMP OF
CERTIFICATION

FOR ADULTS CAPABLE OF GIVING CONSENT:

Printed Name of Child: _____

Child's Date of Birth _____ / _____ / _____

Child's Gender Male Female

PLEASE CHECK ONE:

YES, I want my child to participate NO, I do not want my child to participate

Printed Name of Parent/Guardian: _____

Phone Number: (_____) _____ - _____
area code

Address: _____
Street

City _____ State _____ Zip
code _____

SIGNATURE of Parent/Guardian: _____ Date _____

NOTE: A COPY OF THE SIGNED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY OF THE CONSENT FORM MUST BE PROVIDED TO THE PARTICIPANT

FOR OFFICE USE ONLY:
STUDY APPROVED FOR ENROLLMENT OF: ___ Adults Only Adults and Children ___
Children Only

Site Research:
Baltimore City Public Middle Schools



A valid OMB number is located in the heading of this document in accordance with the Paperwork Reduction Act of 1995. Failure to display a valid OMB number permits a respondent to raise the affirmative legal defense provided by the "public protection" provision.

RESEARCH PARTICIPANT ASSENT FORM

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments or regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH,

Application No.: 03-04-07-08

Sponsor: The National Institute of Child Health and Human Development
Rockville, MD

Principal Investigator: Tina Cheng, MD, MPH
Director, Division of General Pediatrics and Adolescent Medicine
The Johns Hopkins University School of Medicine

Date/Revision: April 19, 2006

ABOUT THE STUDY

I am being asked if I want to be in the **Steppin' Up Program** for 6th graders at my middle school. The goal of the program is to help kids stay involved in school, get along with family and friends, and stay healthy and safe. If I say yes, I will be part of a study to see if the program works.

If I say 'yes,' I will:

1. Answer questions on a survey during class time two to three times a year in 6th, 7th, and 8th grade. The questions will be about my feelings about school, safety, health, and time spent with my friends and family.
2. I will learn about how to get along with others, solve problems, and stay involved in school.
3. Allow **Steppin' Up** researchers to get my grades and my disciplinary record from my school.
- 4.
5. If I say 'yes,' I will get information about how it is important to stay involved in school and be healthy and safe. I may also be assigned to the weekly **Steppin' Up Program** held either in the fall or spring of my 6th grade year. I understand that the program will be held during school and
6. sometimes after school. The program will include fun projects led by a session leader and other
- 7.
8. adults. Adults from the program may also call me on the phone or visit me at home to talk about school and staying healthy and safe.
- 9.
10. I may have my picture taken or make a videotape as part of some **Steppin' Up** projects. I know that pictures and videos will be used for activities that are part of the **Steppin' Up** Program and may also be used to show the **Steppin' Up Program** on the school's TV channel or in **Steppin' Up** newsletters.
- 11.
12. I can choose to be in this study or not. If I say 'no,' no one, even the teachers and staff at school, will treat me any differently than before the study. If I say 'yes' now and change my mind later, I know I can stop at any time. I just have to tell the program staff that I don't want be in the program any longer.
- 13.

14. It is possible that someone not involved in the study may see information I give. But, program staff will not tell anyone what I give or tell them, unless I say I plan to hurt myself or someone else, that an adult has hurt me, or if I report a sexually transmitted disease. In these cases the law says they must report it.

15.

16. I know that the research team has a Certificate of Confidentiality for this study. The certificate protects my privacy because it lets the researchers refuse to give out information that would identify me in civil, criminal, or other legal actions, unless the information has to be reported by law, such as in the cases stated above.

17.

18. Also, I know that I do not have to answer any survey questions I do not want to answer.

19.

20.

21. **ASSENT**

22.

23. What I have read about the ***Steppin' Up Program*** makes sense to me and I agree to be in it.

24.

25.

26.

27. _____

28. Student sign here for Assent

Date

29.

30.

31.

32.

33. Highlandtown Middle School #133

34. 101 S. Ellwood Avenue

35. Baltimore, MD 21224

36. Phone 410-396-9133

37. Fax 410-396-9286

38.

o *Ms. Veronica Dixon*

Principal

September 7, 2005

Dear Parent:

Welcome to Highlandtown Middle School. I am pleased to tell you about an exciting program for our 6th grade students. ***Steppin' Up***, a program at the Johns Hopkins University, is part of a research project which aims to learn more about how to best support the social and learning

needs of our children. Some children will attend weekly activities for a semester during their 6th grade year. They will learn problem-solving skills, how to get along with others, and how to stay involved in school. All children and parents in the program will receive helpful information on these topics.

In this packet, you will find information on ***Steppin' Up*** and a consent form that describes the project and the services you and your child may receive from the program. As parent permission is needed to take part in the program, please complete the attached form and have your child return it to his/her homeroom teacher as soon as possible. We need to have all forms returned, regardless of your decision.

I fully support the goals of this project and will work with program staff during the year to insure that our students achieve success. If you have any questions or would like to learn more about the ***Steppin' Up Program***, please feel free to contact me or Ms. Shenita Baldwin, ***Steppin' Up*** School Liaison, at 410-396-9133.

Sincerely,

Ms. Veronica Dixon
Principal

Paul Laurence Dunbar Middle School, # 133

**500 N. Caroline Street
Baltimore, MD 21205
Phone 410-396-9296
Fax 410-396-2954**

Ms. Betty Donaldson

Principal

September 7, 2005

Dear Parent:

Welcome to Paul Laurence Dunbar Middle School. I am pleased to tell you about an exciting program for our 6th grade students. ***Steppin' Up***, a program at the Johns Hopkins University, is part of a research project which aims to learn more about how to best support the social and learning needs of our children. Some children will attend weekly activities for a semester during their 6th grade year. They will learn problem-solving skills, how to get along with others, and how to stay involved in school. All children and parents in the program will receive helpful information on these topics.

In this packet, you will find information on ***Steppin' Up*** and a consent form that describes the project and the services you and your child may receive from the program. As parent permission is needed to take part in the program, please complete the attached form and have your child return it to his/her homeroom teacher as soon as possible. We need to have all forms returned, regardless of your decision.

I fully support the goals of this project and will work with program staff during the year to insure that our students achieve success. If you have any questions or would like to learn more about the ***Steppin' Up*** program, please feel free to contact me or Ms. Mary Carter-Cross, ***Steppin' Up*** School Liaison, at 410-396-9133.

Sincerely,

Ms. Betty Donaldson
Principal

Chinquapin Middle School #46
900 Woodbourne Avenue
Baltimore, MD 21212
Phone 410-396-6424

Ms. Deborah King
Principal

December 15, 2005

Dear Parent:

Happy Holidays from Chinquapin Middle School! I am pleased to tell you about an exciting program for our 6th grade students. ***Steppin' Up***, a program at the Johns Hopkins University, is part of a research project which aims to learn more about how to best support the social and learning needs of our children. Some children will attend weekly activities for a semester during their 6th grade year. They will learn problem-solving skills, how to get along with others, and how to stay involved in school. All children and parents in the program will receive helpful information on these topics.

In this packet, you will find information on ***Steppin' Up*** and a consent form that describes the project and the services you and your child may receive from the program. As parent permission is needed to take part in the program, please complete the attached form and have your child return it to his/her homeroom teacher as soon as possible. We need to have all forms returned, regardless of your decision.

I fully support the goals of this project and will work with program staff during the year to insure that our students achieve success. If you have any questions or would like to learn more about the ***Steppin' Up Program***, please feel free to contact me or Ms. Sheryl Wright, 6th grade administrator.

Sincerely,

Ms. Deborah King
Principal

**Let's get to *Steppin' Up*
today!**

To learn more,
contact Nadine Finigan,
Project Manager, at
443-287-3215

**Remember!
Parent permission is needed
for you and your child to take part in
Steppin' Up.
Sign a permission slip today!**

Highlandtown Middle School and

The Johns Hopkins University
School of Medicine

Present...



A program to:

Help kids make good choices
and feel good about school

Help parents stay involved
in their child's schooling



Many students have a hard time
adjusting to middle school. If
students could learn more about how to

- ✓ do well in school
- ✓ set goals and achieve them
- ✓ get along with others
- ✓ school would be so much more fun!

✓ *Steppin' Up* wants to help parents stay involved in this transition. ✓

What is *Steppin' Up*?

- ✓ The *Steppin' Up* Program includes:
 - ✓ Sessions during the school day
 - ✓ After-school activities
 - ✓ One-on-one mentoring
 - ✓ Field trips
 - ✓ Community breakfasts



✓
✓ Parents have the opportunity
✓ to become involved by participating in parent sessions. In sessions, parents will learn new ways to help their children do
✓ well in school and stay out of trouble. ✓



✓ How can my child and I participate in ***Steppin' Up?***

- ✓ Get a permission slip from the school,
- ✓ sign it, and return it today!



✓ WHO:

- ❖ Incoming 6th grade students & their parents
- ❖ Parent permission is required.

✓ WHAT: ***Steppin' Up*** is a fresh, fun, & engaging program for kids.

❖ *What will kids learn about?*

- ✓ Study skills
- ✓ Organization, goal-setting, classroom behavior, & school involvement addressed 1st in program sessions
- ✓ Character
 - ✓ Learning to have empathy, recognizing different emotions in self & others, & how to handle strong feelings (like anger)
- ✓ Relationships

- ✓ How to make new friends, cooperation skills, working through problems with others, & appreciating diversity
 - ✓ Becoming involved in positive activities in the community
 - ✓ *How will kids learn these skills?*
 - ✓ Positivist Approach
 - ✓ Possible Selves
 - ✓ Group Mentoring
 - ✓ Community Connections
 - ✓ *Where will kids learn these skills?*
 - ✓ All **Steppin' Up** students will receive useful materials that address
 - ✓ program goals.
 - ✓ Some **Steppin' Up** students will also attend weekly group sessions during school.
 - ✓ *Behavior Management*
 - ✓ *Token economy* system to reward good behavior & extra effort & to redirect students when they get off track
 - ✓ *Don't forget the parents!*
 - ❖ Newsletters
 - ✓ Emphasize program goals
 - ✓ Include tips for parents
 - ✓ Provide updates on **Steppin' Up** classroom activities
 - ✓
 - ❖ Parents for Education!
 - ❖ In-home sessions to help parents help their children adjust to middle school
 - ❖



WHY:

- ❖ To help students with the transition to middle school
- ❖ To help students improve their skills & behavior so teachers will need to spend less time on activities that take away from required curricular learning



WHEN: Newsletters

o **Sent home quarterly**

Program Sessions

1 day per week during students' SPAR period

Each student will attend a **Steppin' Up** session once per week. Occasional field trips for students will also be planned.

Parent Workshops

4 - 6 times during the school year
Held at the parents' convenience

HOW:

Steppin' Up Program sessions will be directed by a session leader from the Johns Hopkins staff who is trained in the program goals & objectives. Trained adult mentors will participate in group activities.

Testing the Program

- ❖ **Steppin' Up** students will complete a survey (one hour in class) each fall & spring from 6th – 8th grade about the program & attitudes & behaviors related to school involvement & staying healthy and safe.
- ❖ **Steppin' Up** parents will be asked to complete up to four 20-minute surveys in the fall & spring of their child's 6th grade year & in the spring of his/her 7th and 8th grade years.
- ❖ *For more information, please call Nadine Finigan, Project Manager, at 443-287-3215, or email at nfiniga1@jhmi.edu.
- ❖
- ❖
- ❖
- ❖