

Partners HealthCare System Research Consent Form

Parent Template
Version Date: August 2016

Subject Identification

Protocol Title: Implementation and Evaluation of a Before School Physical Activity Program in Revere, MA

Principal Investigator: Elsie Taveras, MD

Site Principal Investigator:

Description of Subject Population: Students, grades K-8, in Revere, MA.

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about giving permission for your child to take part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you and your child. If you decide to give permission for your child to take part in this research study, you must sign this form to show that you want him/her to take part. We will give you a signed copy of this form to keep.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Why is this research study being done?

Your child’s school is participating in the BOKS (Build Our Kids’ Success) Program. BOKS is a **free, before school physical activity program** to get kids moving in a fun way to get their bodies and minds ready for the school day. Each session includes a warm-up, skill of the week, and fun group games. One BOKS session ran in **Spring 2018** and a second BOKS session will begin this **Fall 2018**.

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The BOKS program will occur at your child's school, approximately 1 hour **before school, three times a week, this fall.**

- At Paul Revere Innovation School, the program will run for **15** weeks from September through January.
- At Beachmont Elementary School and Garfield Middle School, the program will run for **12** weeks from October through December.

You will receive a handout from your child's school with the exact start and end dates of the BOKS program.

We are working with your child's school to study how before school physical activity may affect children's school performance, physical health, and emotional health. Other research studies have shown that BOKS may help children stay at a healthy weight and improve social wellness. This study hopes to learn more about how it may also affect school performance.

Participation in this research study is **optional** and will not affect participation in the BOKS Program. Regardless of study participation, the BOKS program expects children to attend at least 80% of the sessions so they can get the most out of it.

About 240 students will participate in this research study across three schools in Revere, MA. In your child's school, about 80 children will take part in the study. Half of these children participated in the Spring 2018 BOKS program, the other half will participate in the Fall 2018 BOKS program.

If your child already enrolled in the study in Spring 2018, you do not need to complete this form. However, if you **do not** want them to continue to participate in the study this fall, you can contact Dr. Rachel Whooten at 617-643-4585.

This study is funded by the Massachusetts General Hospital Executive Committee on Community Health, Reebok Foundation, and the American Council on Exercise.

How long will my child take part in this research study?

This study will last about 3-4 months. We will collect data during the Fall 2018 BOKS session. In the future, you may be invited to participate in follow-up studies.

What will happen in this research study?

In this research study, both you and your child will help us learn about how physical activity may benefit children. Below, we describe what will happen if you and your child agree to participate in this study.

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If you and your child would only like to participate in the BOKS program and not the research study, you only need to complete the BOKS Registration Form. **Regardless of study participation, your child may participate in BOKS.**

As there is only room for approximately 40 children within each school for the BOKS program, enrollment will be on a first-come, first-serve basis.

What will happen in the research study?

The study will include the following parts:

- (1) Trained research staff will visit your child's school at the beginning of the BOKS program and at the end of the BOKS program to collect the following information:

All Children:

- Height
- Weight

Children over 8 years old:

- A short survey about your child's health, feelings, relationships and life at school of physical, emotional, social, and school functioning (5 minutes)
- A 10-15 minute iPad game that measures how your child pays attention and helps us learn about how your child thinks

This information will be collected for all study participants.

- (2) Trained research staff will also be present at BOKS sessions to observe how kids are being active. At some of these sessions (1-3 total), your child will wear an activity monitor that will record their total movement for the BOKS session.
- (3) At the start and end of the session, you will receive a short survey mailed to your home. This survey will ask questions about your child's health and behaviors, and how physical activity fits into your family's life.
- (4) If you agree to participation in this study, your child's school will also share information with us about his/her grades, school attendance, and behavior in school. All information shared will be confidential.

What are the risks and possible discomforts from being in this research study?

There are no major risks involved with being in this study. There is a small risk of loss of confidentiality whenever personal or medical information is collected for research, but we take precautions to protect your child's information and use a random number instead of your child's name to identify you whenever possible.

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There is also a chance that during the surveys you or your child may feel uncomfortable with some questions, but you do not have to answer anything you don't want to. We will be measuring height and weight, and this may be sensitive to some children. We will make every effort to keep these measurements private.

Lastly, as BOKS is a physical activity program, there is always the risk of injury from being active. This risk of injury is not known to be higher than that of participating in your child's school's gym class.

For your child's safety, they should wear clothing that is suitable for being active, including sneakers and comfortable clothing.

What are the possible benefits from being in this research study?

You and your child are not expected to directly benefit from this study. We hope the study will help us to better understand the relationship between physical activity and children's health.

Can my child still get medical care within Partners if s/he doesn't take part in this research study, or if s/he stops taking part?

Yes. Your decision won't change the medical care your child gets within Partners now or in the future. There will be no penalty, and you won't lose any benefits your child receives now or has a right to receive.

Taking part in this research study is up to you. You can decide not to permit your child to take part. If you decide to permit him/her to take part now, you can change your mind and have him/her drop out later. We will tell you if we learn new information that could make you change your mind about your child taking part in this research study.

What should I do if I want my child to stop taking part in the study?

If your child takes part in this research study, and you want him/her to drop out, you should tell us. We will make sure that your child stops the study safely. We will also talk to you about follow-up care for your child, if needed.

Also, it is possible that we will have to ask your child to drop out of the study before s/he finishes it. If this happens, we will tell you why. We will also help arrange other care for your child, if needed.

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Will my child or I be paid to take part in this research study?

You and your child will both receive compensation for participation in this research study. You will receive a \$5 gift certificate to Target via the mail following return of each parent survey. Your child will receive \$2 mailed home after each study visit that occurs in school (up to \$8 total).

What will I have to pay for if my child takes part in this research study?

We do not anticipate you will need to pay for anything as a result of being in this study. Study funds will pay for certain study-related items, such as the activity monitoring device, and services, such as the school visits.

What happens if my child is injured as a result of taking part in this research study?

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or your child or give you other compensation for an injury, should one occur. However, you or your child are not giving up any of your legal rights by signing this form.

If you think your child has been injured or has experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Elsie Taveras is the person in charge of this research study. You can call her at 617-726-8555, Monday-Friday 9-5. You can also call Dr. Rachel Whooten at 617-643-4585, Monday-Friday, 9-5, with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Dr. Whooten at 617-643-4585.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

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You can talk to them about:

- Your child's rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to give permission for your child to take part in this research study, or to continue with it, they want to know and can help.

If my child takes part in this research study, how will you protect my child's privacy?

During this research, identifiable information about your child's health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your child's health information for research and why they may need to do so.

In this study, we may collect health information about your child from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your child's identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs
- People from organizations that provide independent accreditation and oversight of hospitals and research

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- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to your child or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your child's health information might not have to follow the same privacy rules that we follow and might use or share your child's health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your child's health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your child's health information only when we must, and we ask anyone who receives it from us to take measures to protect your child's privacy. The sponsor has agreed that it will not contact your child without your permission and will not use or share your child's information for any mailing or marketing list. However, once your child's information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your child's health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your child's name or other identifying information **will not** be used for these purposes without your specific permission.

Your Child's Privacy Rights

You have the right **not** to sign this form that allows us to use and share your child's health information for research; however, if you don't sign it, your child can't take part in this research study.

You have the right to withdraw your permission for us to use or share your child's health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, your child cannot continue to take part in the study.

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If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your child's health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Parent(s)/Guardian for Child:

I give my consent for my child to take part in this research study and agree to allow his/her health information to be used and shared as described above.

Parent(s)/Guardian for Child

Date

Time (optional)

Parents(s)/Guardian for Child

Date

Time (optional)

Consent Form Version Date: 8/6/2018