

Version Date: 06/19/2026

CONSENT FOR RESEARCH
The Pennsylvania State University

Title of Project: Basketball Rx: Game-Changing Health – Combating Adolescent Obesity and Mental Health with Hoops & Health Education

Principal Investigator: Sarah Inés Ramírez, MD, FAAFP

Address: 500 University Drive
Hershey, PA 17033

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. and after hours (717) 232-5443

Email Address: BasketballRx@pennstatehealth.psu.edu

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you, and there will be no penalty or loss of benefits to which you are entitled.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

Because the people in this study are under 18 years old and cannot give consent on their own, we will ask their legal guardian(s) to give permission for them to take part. We will also ask the children to agree (give assent) to join the study. In the consent form, when we say “you,” we mean you or your child.

KEY INFORMATION

The following is a short summary of this study to help you decide whether or not to be a part of this research. More detailed information is provided later in this form. If you have any questions, be sure to ask the study team.

Why am I being invited to take part in this research study?

We are asking you to take part in this voluntary research study because you have a BMI of 85% or greater.

What is the purpose of this research study?

The purpose of this voluntary research study is to create a basketball-based exercise program in Harrisburg, PA, to educate children with obesity on nutrition and exercise and promote healthy habits and long-term well-being.

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How long will the research study last?

The study will be conducted over the course of 3 months. The study participants will attend 6 sessions across 3 months. Sessions 1 through 5 will be one and a half hours long. Session 6 will be three hours long.

What will I need to do?

Your child will attend six sessions. You will be expected to stay with them during all sessions. At the first and last sessions, we will measure your child's height, weight, waist size, blood pressure, and heart rate, and they will answer questions about their mood and habits. They will also get a fitness tracker and water bottle at the first session and a basketball uniform at the last session. Each session includes a health class and a basketball class. At the final session, your child will give a short presentation and play in a basketball tournament. You will receive two gift cards—one after the first session and one after the last session.

What are the main risks of taking part in the study?

This study involves physical activity and is considered low to moderate risk. However, there are some potential risks, including:

- Minor physical injury, such as muscle soreness, sprains, or falls, may occur during running, jumping, or basketball drills.
- Fatigue or shortness of breath, especially if participants are not accustomed to physical exercise.
- Emotional discomfort, such as frustration or embarrassment, during group activities or games.
- Loss of confidentiality, although steps will be taken to protect participants' privacy.

All activities will be age-appropriate and led by trained staff. Participants will be encouraged to take breaks as needed, and staff will monitor for signs of discomfort or fatigue. Any injuries or concerns will be addressed immediately.

What are the possible benefits to me that may reasonably be expected from being in the research?

We cannot promise any benefits to you from taking part in this study. However, possible benefits include increasing knowledge about nutrition and learning how to maintain healthy habits (e.g., healthy eating, sleep, relaxation techniques) and exercise. Results of the study may benefit other people in the future by helping us learn more about how best to help patients learn about healthy eating and exercise.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. You may choose not to take part in this research study.

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. Why is this research study being done?

This research is being done to find out if it is possible to reduce BMI and improve mood among adolescents through structured physical activity, enhancing health literacy on nutrition, exercise, and lifestyle modifications, and promoting community involvement. Approximately 30 people will take part in this research study.

2. What will happen in this research study?

If you join the study, your child will come to six sessions.

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At the first session:

- We will check your child's height, weight, waist size, blood pressure, and heart rate.
- Your child will answer questions about how they feel and their daily habits.
- They will get a free fitness tracker and water bottle to keep.
- They will join a 90-minute session which includes a 40-minute health class and a 50-minute basketball class.
- You will get the first gift card by email.

At sessions 2 through 5:

- We will check your child's blood pressure and heart rate at the beginning of each session.
- Your child will attend a 90-minute session which includes a 40-minute health class and a 50-minute basketball class.
- Sessions 2 through 5 are 90 minutes per visit which totals 6 hours.

At the last session:

- We will check your child's height, weight, waist size, blood pressure, and heart rate again.
- They will answer the same questions as in the first session.
- They will get a basketball uniform to keep.
- They will give a short presentation on something they learned during a health fair and play in a short basketball tournament.
- You will receive the second gift card by email.
- This last session (session 6) will last 3 hours.

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

This study has been designed to be very safe, with very little risk to children. During all sessions, a doctor and a medical resident will be there to watch for any problems, and guardians will be there too. If your child gets hurt or seems upset, the study staff will write it down and help right away. If there is an emergency, we will tell you to get medical help right away. If it's not an emergency, we will ask you to follow up with your child's regular doctor at the Penn State Health Harrisburg Clinic.

Because this study includes playing basketball, there is a small chance your child may get minor injuries like scrapes, bruises, or muscle soreness. There is also a small risk of more serious injuries, such as sprains or falls, just like in any regular sports activity. We will do our best to keep the activities safe and make sure children are using proper techniques.

We will also review any notes and feedback from families during the study to make sure everything stays safe. If we notice anything concerning, we may change the study to better protect the children.

Some of the survey questions might feel uncomfortable, but your child does not have to answer any questions they don't want to. We will work hard to keep your child's information private by storing it in a secure Penn State research system. Only the study team will be allowed to see it. However, there is a small risk that someone outside the study could see this information. We will follow the law and use the best tools available to keep it safe, but we can't promise complete confidentiality.

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

4a. What are the possible benefits to me?

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By taking part in this study, kids may have some benefits, like:

- Learning more about healthy eating, exercise, mindfulness, and good sleep habits to help them make healthier choices.
- Getting more exercise through fun basketball sessions with guidance and support.
- Possibly lowering their body weight and waist size by being more active and making healthier choices.
- Feeling more confident and making healthier choices by getting support, working in a team, and setting goals.

4b. What are the possible benefits to others?

If this study goes well, it could help make basketball and healthy eating programs for kids in other places. It might help doctors and teachers learn better ways to help kids stay healthy and feel good. What we learn from this study can help us plan bigger studies to help more kids live healthier lives.

5. What other options are available instead of being in this research study?

You do not have to let your child take part in this study to get care or support for their health. Instead of participating in this research, your child can:

- Follow the advice from their doctor about healthy eating, exercise, and sleep.
- Choose not to make any changes to their current habits.

Before you decide, we will talk with you about all the options available for your child. We will explain the possible benefits and risks of each option.

Because this is a new program, it is only available to children who take part in this study.

6. How long will I take part in this research study?

If you agree to take part, it will take you about 3 months to complete this research study. You will be asked to visit the research site 6 times. Sessions 1 through 5 will each last 1.5 hours. Session 6 will last 3 hours.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information to people who need to review this information. Reasonable efforts will be made to keep the personal information in your research record private. However, absolute confidentiality cannot be guaranteed, and there may be situations where disclosure is required by law.

- Your research records will be labeled with your code number and will be kept in a safe area in Dr. Sarah Inés Ramírez's office.
- In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.
- We will only use pictures of your child in publications or presentations if you have given us permission to take and use those images during the study.

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We will do our best to keep your child's participation in this research study confidential to the extent permitted by law. However, the following people/groups may check and copy records about this research.

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- The research study sponsors, Highmark Blue Shield and Aetna
- The Penn State Institutional Review Board (a committee that reviews and approves human research studies) and the Penn State Human Research Protection Program
- The investigator, Penn State study staff, and other Penn State professionals who may be evaluating the study or need this information to do their jobs (such as for treatment, payment (billing), or health care operations)

The research team may use your past, present, and future medical information and records for the purpose of your participation in the research study specifically identified in this authorization. Information that will be disclosed may include information developed as a result of the research study, information that identifies you, and information in your medical record, such as HIV/AIDS diagnosis, drug/alcohol treatment and mental health data. Your authorization will remain in effect until you revoke it. You may change your mind and revoke (take back) this authorization at any time and for any reason. However, any information previously disclosed under this authorization may not be retrieved and may no longer be protected by federal or state privacy laws. To revoke this consent and authorization, contact the Principal Investigator using the information found on the first page of this form. Revocation of, or refusal to sign, this consent and authorization will not impact the care you receive at Penn State that is not related to the research; however, you will be excluded from participation in this research study if you do not provide this consent and authorization.

7b. What will happen to my research information after the study is completed?

We may use your research information in future studies or may share your information with other investigators for future research without your additional informed consent. Before we use or share your information, we will remove any information that shows your identity.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

There is no cost to you for taking part in this study.

8b. What happens if I am injured as a result of taking part in this research study?

It is possible that your child could incur injuries because of being in this research study. If this happens and emergency medical treatment is required, seek treatment immediately at any medical facility. If they experience an injury and believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment. You should also let any healthcare provider who treats your child know that they are in a research study.

Penn State compensation for injury

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- There are no plans for Penn State to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

When you sign this form, you are not giving up any legal right to seek injury compensation.

9. Will I be paid to take part in this research study?

You will be eligible to receive up to \$100 for your child's participation in this research study, \$50 at the end of session 1 and \$50 at the end of session 6. To receive the 2nd \$50 gift card, your child must attend at least 3 sessions before session 6.

10. Who is paying for this research study?

The sponsors, Aetna and Highmark Blue Shield, are paying Penn State for the research to be done.

11. What are my rights if I take part in this research study?

Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

If you withdraw from the study early, your data may still be included in the analysis where appropriate and will be deidentified before analysis. During the research you will be provided with any new information that may affect your child's health, welfare, or your decision to continue participating in this research.

12. If I have questions or concerns about this research study, whom should I call?

Please call the head of the research study, Sarah Inés Ramírez at (717) 232-5443.

You may also contact the Penn State Human Research Protection Program (HRPP) at (814) 865-1775 or visit the HRPP website at <https://researchsupport.psu.edu/orp/irb/information-for-participants/> if you:

- Have questions or want information regarding your rights as a person in a research study.
- Have concerns, complaints, or general questions about the research.
- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

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Optional Storage of Photographs for Future Research

In the main part of this study, we are collecting photos of participants playing basketball and participating in the health class that contain identifiable information from you. Photographs will be taken of participants during the sessions. Facial images may be captured in these photographs. If you agree, the researchers would like to maintain these photos to be used in publications or at presentations.

Your photos will be labeled with a code number.

- The length of time they will be used is unknown.
- You will be free to change your mind at any time.
- You should contact principal investigator if you wish to withdraw your permission for your recordings to be used for future research or publicly. The recordings will then be destroyed and not used for future research studies or shown publicly.

You should initial below to indicate what you want regarding the storage your photos for publications or presentations

b. Your identifiable photos may be shared publicly at presentations or in publications.

_____ Yes _____ No

INFORMED CONSENT TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative, provided the subject or subject representative an opportunity to discuss and consider whether or not to participate in the research, and have answered any questions about the research.

_____	_____	_____
Signature of person who explained this research	Date	Printed Name
(Only approved investigators for this research may explain the research and obtain informed consent.)		

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Talked about this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

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Signature of Parent(s)/Guardian for Child

By signing this consent form, you indicate that you permit your child to be in this research and authorize your child's information to be used and shared as described above.

Printed name of child

Signature of Parent/Guardian Date Printed Name

☐ **Parent**

☐ **Individual legally authorized to consent to the child's general medical care. (See note below.)**

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child's general medical care. Contact legal counsel if any questions arise.

Subject's Legally Authorized Representative

By signing below, you indicate that you give permission for the subject to be in this research and authorize the subject's information to be used and shared as described above.

Printed name of subject

Signature of Legally Authorized Representative Date Printed Name

Check the applicable box below indicating authority to act for subject:

☐ Court-appointed legal guardian

☐ Health Care Power of Attorney

☐ Health Care Representative: _____
Relationship to Subject